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Humane-Slaughter Legislation . . . .
A. R. MILLER

The Scope of Pending Color-Additives Legislation . . . . . .
EDWARD BROWN WILLIAMS

Proposed Color-Additives Amendment .
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A COMMERCE CLEARING HOUSE PUBLICATION

PUBLISHED IN ASSOCIATION WITH THE FOOD LAW INSTITUTE, INC.

The editorial policy of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need. The editorial policy also is to allow frank discussion of food-drug-cosmetic issues. The views stated are those of the contributors and not necessarily those of the publishers. On this basis, contributions and comments are invited.

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Charles Wesley Dunn

It is our sad duty to record the death of Charles Wesley Dunn, chairman of our editorial advisory board from the beginning of publication in 1946. Mr. Dunn, 74, died of a heart attack at his home at Wilson Point, South Norwalk, Connecticut, on November 2. He was the author of numerous authoritative treatises and articles on the food and drug laws, and he was also a prominent figure in the field of corporation and antitrust laws.

Mr. Dunn, who had practiced law in New York City since 1911, was generally recognized as the "dean of food and drug lawyers." At the time of his death, he had been general counsel for Grocery Manufacturers of America for more than 45 years. He was general counsel for Premium Advertising Association of America and until recently had been counsel for American Pharmaceutical Manufacturers' Association. He was a director of Swiss-American Corporation.

In the area of public service, Mr. Dunn was president of The Food Law Institute, Inc.; professor of law at New York University, heading graduate instruction in food and drug law; a member of the National Citizens Advisory Committee on the Food and Drug Administration and of the Attorney General's National Committee to Study the Antitrust Laws; public trustee of The Nutrition Foundation; and member of the liaison panel of the Food Protection Committee, Food and Nutrition Board, National Research Council, National Academy of Sciences.

1885 – 1959

Mr. Dunn's bar association activities were extensive. Only a few can be mentioned here: chairman of the Division of Food, Drug and Cosmetic Law in the Section of Corporation, Banking and Business Law of the American Bar Association, and member of the section's council; chairman of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association, and member of the association's executive committee; member of the Inter-American Bar Association, and vice chairman of its Section on Food, Drug and Cosmetic Law. He also served as general counsel of The World Medical Association, United States Committee, Inc., and as a member of its board of directors.

Mr. Dunn, a native of Annapolis, Nova Scotia, came to the United States in his childhood. He leaves his widow, Alice Hafner Dunn; two children—Charles Wesley Dunn, Jr., of New York City, and Mrs. Anne Foster, of Falls Church, Virginia; and one granddaughter, Amy Foster.

Those who have been privileged to work with Mr. Dunn on the FOOD DRUG COSMETIC LAW JOURNAL poignantly regret that his long years of service are now ended. We have always been grateful for his efforts on the JOURNAL and for his untiring cooperation in the advancement of its interests. As a tribute to his memory we shall endeavor to carry on as effectively as he did.

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WASHINGTON-

ACTION AND NEWS

In the Food and Drug Administration

Safe "Food Additives."—Substances which the Commissioner of Food and Drugs regards as generally recognized as "safe" for specified uses in food are listed in a regulation, 21 CFR 121.101, which was published in 24 *Federal Register* 9368, November 20, 1959, effective December 20, 1959. The full text is reproduced below:

Substances that are generally recognized as safe

§ 121.101 (a) It is impractical to list all substances that are generally recognized as safe for their intended use. However, by way of illustration, the Commissioner regards such common food ingredients as salt, pepper, sugar, vinegar, baking powder, and monosodium glutamate as safe for their intended use. The lists in paragraph (d) of this section include additional substances that, when used for the purposes indicated, in accordance with good manufacturing practice, are regarded by the Commissioner as generally recognized as safe for such uses.

(b) For the purposes of this section, good manufacturing practice shall be defined to include the following restrictions:

(1) The quantity of a substance added to food does not exceed the amount reasonably required to accomplish its intended physical, nutritional, or other technical effect in food; and

(2) The quantity of a substance that becomes a component of food as a result of its use in the manufacturing, processing, or packaging of food, and which is not intended to accomplish any physical or other technical effect in the food itself, shall be reduced to the extent reasonably possible.

(3) The substance is of appropriate food grade and is prepared and handled as a food ingredient. Upon request the Commissioner will offer an opinion, based on specifications and intended use, as to whether or not a particular grade or lot of the substance is of suitable purity for use in food and would generally be regarded as safe for the purpose intended, by experts qualified to evaluate its safety.

(c) The inclusion of substances in the list of nutrients does not constitute a finding on the part of the Department that the substance is useful as a supplement to the diet for humans.

(d) Substances that are generally recognized as safe for their intended use within the meaning of section 409 of the act are as follows:

CHEMICAL PRESERVATIVES

Ascorbic acid.
Ascorbyl palmitate.

Calcium ascorbate.
Calcium propionate.
Erythorbic acid.
Potassium sorbate.
Propionic acid.
Sodium ascorbate.
Sodium propionate.
Sodium sorbate.
Sorbic acid.
Tocopherols.

BUFFERS AND NEUTRALIZING AGENTS

Acetic acid.
Aluminum ammonium sulfate.
Aluminum sodium sulfate.
Aluminum potassium sulfate.
Ammonium bicarbonate.
Ammonium carbonate.
Ammonium hydroxide.
Ammonium phosphate (mono- and dibasic-).
Calcium carbonate.
Calcium chloride.
Calcium citrate.
Calcium gluconate.
Calcium hydroxide.
Calcium lactate.
Calcium oxide.
Calcium phosphate.
Citric acid.
Lactic acid.
Magnesium carbonate.
Magnesium oxide.
Potassium acid tartrate.
Potassium bicarbonate.
Potassium carbonate.
Potassium citrate.
Potassium hydroxide.
Sodium acetate.
Sodium acid pyrophosphate.
Sodium aluminum phosphate.
Sodium bicarbonate.
Sodium carbonate.
Sodium citrate.
Sodium hydroxide.
Sodium phosphate (mono-, di-, tri-).
Sodium potassium tartrate.
Sodium sesquicarbonate.
Sulfuric acid.
Tartaric acid.

EMULSIFYING AGENTS

Diacetyl tartaric acid esters of mono- and diglycerides from the glycerolysis of edible fats or oils.
Mono- and diglycerides from the glycerolysis of edible fats or oils.
Monosodium phosphate derivatives of mono- and diglycerides from the glycerolysis of edible fats or oils.
Propylene glycol.

MISCELLANEOUS

Acetic acid.
Aluminum sodium sulfate.
Aluminum sulfate.
Butane.
Calcium phosphate, tribasic.
Caramel.
Carbon dioxide.
Carnauba wax.
Citric acid.
Glycerin.
Glycerol monostearate.
Helium.
Magnesium carbonate.
Magnesium hydroxide.
Monoammonium glutamate.
Nitrogen.
Papain.
Phosphoric acid.
Propane.
Propylene glycol.
Triacetin (glyceryl triacetate).
Tricalcium phosphate.
Sodium carbonate.
Sodium phosphate.
Sodium tripolyphosphate.

NONNUTRITIVE SWEETENERS

Calcium cyclohexyl sulfamate.
Calcium saccharin.
Saccharin.
Sodium cyclohexyl sulfamate.
Sodium saccharin.

NUTRIENTS

Ascorbic acid.
Calcium carbonate.
Calcium oxide.

(Continued on page 740)

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Humane-Slaughter Legislation

By A. R. MILLER

Dr. Miller—Director, Meat Inspection Division, United States Department of Agriculture, Washington, D. C.—Presented This Address at the 1959 Meeting of the American Bar Association Division of Food, Drug and Cosmetic Law, at Miami Beach on August 24

MY CHOOSING to discuss with you today the ramifications of humane-slaughter legislation takes liberties with my assigned subject—a discussion of the Federal Meat Inspection Act. Although it is not included in the Federal Meat Inspection Act, the federal humane-slaughter law is administered as part of the federal meat-inspection program.

The meat-inspection program conducts inspection in more than 500 slaughtering establishments located in every significant meat-producing area in this country. This provides first-hand contact and extensive experience with slaughtering methods and problems. It is understandable that the Secretary of Agriculture would delegate to the Meat Inspection Service those responsibilities vested in him under the humane-slaughter law having to do with the designation of slaughtering methods that are recognized under the statute as being humane.

As for the humane-slaughter legislation, interest in its application by the American meat packer who conducts slaughtering transcends any concern that he might have for the penalties contained in the law. This is so whether it is the limitations placed on him by the federal legislation with respect to his contracting with federal agencies or

fines and imprisonments provided by state statute. The packer is primarily concerned with his public relations. He is appalled at the amount of public interest that has been expressed in connection with the enactment, particularly, of the federal legislation. He knows that by offending this public interest he will jeopardize acceptance of his products in the market place.

To give some idea of the public response during the time that the humane-slaughter bills were being considered by the Senate and the House of Representatives, the following quotations have been taken from the *Congressional Record*. These are statements made by Senator Ellender, chairman of the Committee on Agriculture and Forestry, and Senator Humphrey, who served as chairman of a subcommittee of the Committee on Agriculture and Forestry that was organized to conduct hearings on the humane-slaughter bills.

Senator Ellender said: "I have been in the Senate for 22 years and I know of no bill which has provoked more letter-writing and telegraphic communications than the so-called humane slaughter bill which passed the House."

Senator Humphrey was addressing the president of the Senate when he said, "Mr. President, the other House completed action yesterday on the humane slaughter bill, and sent it to the White House for signature. Hundreds of thousands of men and women who have worked energetically for this cause can take great pride in the successful outcome of their dedicated efforts."

I had an opportunity to see the accumulation of letters received by the House Committee on Agriculture in connection with its hearings held on the humane-slaughter bills. There were literally bales of these letters. The members of the committee's staff told me that they had no recollection of ever receiving anything like that amount of correspondence concerning any bill that had ever been before that committee. You can see what I mean when I say that industry's compliance with the terms of humane-slaughter legislation has for its incentive the maintaining of good public relations rather than a concern for avoiding the penalties provided for in the legislation.

Humane-Slaughter Laws Abroad

In European countries and in England, humane-slaughter laws have been in effect for many years. As a result of such laws it has been the practice in those countries, with the exception of kosher slaughter,

to render animals unconscious before delivering the stroke of the knife that severs the blood vessels in the under side of the neck, with resultant bleeding to death of the animal. Two basic stunning devices have been widely used in Europe to render the animals unconscious. Electrical stunning is the one most generally used, and there are several kinds of devices used to deliver the electric shock. All of these devices accomplish unconsciousness in the animal by passing the electrical shock through the brain.

The other device used in Europe to stun the animal produces its effect by mechanical impact applied to the skull of the animal over the brain. This mechanical impact is delivered by what is called a "captive bolt" that is built in the muzzle end of a heavy pistol-like device. This bolt moves back and forth in the barrel of the pistol and is motivated by the discharge of a blank cartridge.

European slaughtering methods had always been regarded as being unsuitable for American production. Animal temperament and rates of slaughter are not comparable. In Europe the rate of slaughter is slow and the animals are tractable. Here the rate of slaughter is fast-moving and the animals are difficult to restrain.

The European slaughtering methods which had the support of humane-slaughter legislation acquired considerable standing as being the humane way to slaughter animals. Europeans, particularly those who took an interest in humane societies, expressed considerable pride as they pointed to the humane practices employed by European and English meat packers.

In this country, by contrast, there was no national humane-slaughter legislation, and European slaughtering methods were not in use here. For all practical purposes, cattle was the only species rendered unconscious before bleeding. Even with cattle, the method of stunning was not with use of the captive bolt nor the electric shock, but with the use of the manually applied knocking-hammer. This is a long-handled, hammer-like device with a head very much like the manually operated spike-driver. The knocker, so-called, would deliver the blow manually to the skull of the animal, using the knocking-hammer.

The blow would render the animal unconscious, the blood vessels in the neck would be severed, and the animal would bleed to death.

Hogs, calves and sheep would not be rendered unconscious before bleeding. They would be hoisted by a hind leg to an overhead rail where

the sticker, so-called, would sever the neck arteries, and the animal would bleed to death. This operation would be fast-moving, and a very respectable number of people felt that the rapidity with which the animal was dispatched accomplished a humane slaughtering operation.

By contrast with European countries and their national humane-slaughter laws, in the United States humane handling of animals, whether at the time of slaughter or otherwise, came under local anti-cruelty to animal laws and ordinances. As cases would come up from time to time under these local laws and ordinances, the cases would turn on specific acts of cruelty rather than serve as a test of the humaneness of conventional slaughtering methods. This was so for the very good reason that there was not available any criterion that could be used in judging current slaughtering practices. European practices could not be convincingly cited in this connection because of the marked dissimilarity between European and American meat-packing operations.

Even so, American industry from time to time experimented with new slaughtering methods. The captive-bolt pistol was tried out by several firms, but meat packers—with the exception of a very few—discarded it in favor of the familiar knocking-hammer. Electrical stunning was tried, but it, too, was discarded. Industry found that electrical stunning, as then developed and used in Europe, produced objectionable hemorrhagic conditions, particularly in the organs of the animal.

It was not until Hormel & Company in its Austin plant developed the carbon-dioxide method of anesthetizing animals at the time of slaughter that anyone in the industry seriously considered making a change in the conventional method of hog slaughter. As originally developed by Hormel, the carbon-dioxide method was adapted to a slaughter rate of 1,000 hogs per hour. Its objective is to completely anesthetize the animal before it is bled.

The hogs are driven into a tunnel-like chamber that contains an atmosphere of carbon dioxide, and they are carried through this chamber on a moving conveyor. The speed of the conveyor and the exposure of each hog is timed carefully so that, as it emerges from the tunnel, it is relaxed and unconscious and ready for bleeding.

This carbon-dioxide installation accomplished several improvements in the slaughtering process for hogs particularly. It eliminated

a difficult step in the conventional slaughtering operation. The conventional hoisting of the live hog by one of its hind legs to the overhead bleeding rail was hard both on the hog that was being hoisted and on the plant employees who had the job of securing the animal's hind leg to the conveyor. The stress of hoisting the animal sometimes produced bruises that reduced the value of its carcass. The job of restraining the live animal for hoisting to the bleeding rail was a hazardous and unpopular job for the packing-house employees.

Proponents of humane-slaughter legislation welcomed the carbon-dioxide development. As demonstrated by the Hormel installation, here is a way to render hogs unconscious prior to bleeding; it is adaptable to the American fast-moving operation and it handles animals that are otherwise difficult to restrain. There has been one drawback, however—so far the installations have been confined to large-capacity hog slaughterers and the equipment is expensive.

Legislative History

While the development of the carbon-dioxide immobilization of hogs cannot be said to trigger the movement to obtain a federal humane-slaughter law, it certainly set the stage for the proponents of the legislation to point out that there is now available a humane slaughtering method that fits the American needs and, furthermore, has certain operating advantages. This, along with the mechanical stunning method that employs the captive-bolt pistol, in the words of the proponents of the new legislation at the several hearings, gives the American meat packer practical methods that he might adopt advantageously to render all animals unconscious before being bled.

The points of attack were the knocking-hammer as it was used on cattle and the hoisting device that was used to raise the live animal secured by its hind leg to the overhead bleeding rail.

At the hearings witnesses severely criticized the knocking-hammer. The harsh-sounding term "poleax" was used by witnesses when they discussed the knocking-hammer. They emphasized that the manually applied poleax did not with any degree of certainty render the animal unconscious with a single blow. They described how, because of the inaccuracy of the first blow, they had seen knockers repeatedly strike the head of conscious animals with the poleax before rendering the animal unconscious. The discredited knocking-hammer and the emphasis on the importance of rendering the animal unconscious with a single blow pointed up the usefulness of the mechanical

stunner which, it was testified, could locate the stunning blow with a high degree of accuracy. The mechanical stunner was regarded by the witnesses as the device that could accomplish the single-blow objective.

In describing the hoisting of conscious animals to the bleeding rail, the witnesses overlooked no dramatic detail. The slaughtering of animals when viewed for the first time is a somewhat disquieting experience even when it is performed under the best possible conditions. It is difficult for the viewer to appraise impersonally what he sees. The tendency to ascribe human characteristics to animals has always been a complicating phenomenon when considering the subject of animal slaughter. In any case, considerable testimony was directed to the proposition that the proposed legislation should require animals to be rendered unconscious prior to the bleeding.

As the hearings progressed, it became clear that the proponents of the legislation were concerned with two steps in the slaughtering operation. Witnesses pointed out that not only must the animal be slaughtered humanely but also the handling of the animal in connection with its slaughter must be done humanely. The testimony supported the requirement that, in order for the entire slaughtering operation to be done humanely, the animal must be unconscious before there is any shackling, hoisting, throwing or casting of the animal preparatory to bleeding.

Members of rabbinical organizations testified with respect to kosher slaughter. These witnesses pointed out that ritual requirements of the Jewish faith provide that the kosher slaughter be performed on conscious animals using a prescribed bleeding procedure. The early versions of the humane-slaughter bills recognized the ritualistic bleeding procedure as being humane but made no mention of the preparatory handling of the animal. Witnesses explained that the bleeding of a conscious animal is an essential element of kosher slaughter and the bill as finally drafted took care of this.

Federal Humane-Slaughter Law (7 USC Sections 1901-1906)

The testimony that would outlaw the so-called "poleax" and discontinue the hoisting of conscious animals to an overhead bleeding rail is reflected in the statute, which reads:

> Section 1902(a). In the case of cattle, calves, horses, mules, sheep, swine, and other livestock, all animals are [to be] rendered insensible to pain by a single blow or gunshot or an electrical, chemical or other means that is rapid and effective, before being shackled, hoisted, thrown, cast, or cut . . . .

In view of the legislative history, the words "or other means" could not be interpreted as including the manually operated knocking-hammer. It is also clear that the shackling or hoisting of conscious animals is regarded as not being humane. It might be observed at this point that the word "livestock" is not interpreted as including poultry.

Sections 1904 and 1905 of the act give in some detail the powers and responsibilities vested in the Secretary of Agriculture. Witnesses at the hearings devoted a good deal of testimony to the need for research and investigation to enable the secretary to decide just what methods of slaughter might be regarded as being humane. This resulted pretty much from the developing uncertainty that European methods and experiences might not be entirely applicable to conditions in this country. There was also testimony that considered it to be desirable that the secretary should have the assistance of an advisory committee, with membership drawn from various segments of the public that have an interest in humane slaughter. The following quotations are excerpts from the statute in this connection, and they omit much of the detail:

> Section 1904. In furtherance of the policy expressed herein, the Secretary is authorized and directed . . .
>
> (a) to conduct, assist, and foster research, investigation, and experimentation to develop and determine methods of slaughter and the handling of livestock in connection with slaughter which are practicable with reference to the speed and scope of slaughtering operations and humane with reference to other existing methods and then current scientific knowledge;
>
> (b) on or before March 1, 1959, and at such times thereafter as he deems advisable, to designate methods of slaughter and of handling in connection with slaughter which, with respect to each species of livestock, conform to the policy stated . . . [herein].
>
> (c) to provide suitable means of identifying the carcasses of animals inspected and passed under the Meat Inspection Act that have been slaughtered in accordance with the public policy declared . . . [herein].
>
> Section 1905. To assist in implementing the provisions of Section 1904 . . . the Secretary is authorized to establish an advisory committee. . . .

The section on the advisory committee contains considerable detail as to membership, meetings, compensation, and instructions for the committee to make recommendations to the secretary.

During the hearings there was considerable discussion as to whether the humane-slaughter legislation should be mandatory or merely expressed in language that would authorize the secretary to make a study of slaughtering methods in terms of humaneness. The proponents who favored compulsory legislation prevailed, and there

was considerable discussion as to just what should be the penalty for nonconformance. As might be expected, the plight of the small slaughterer was kept well in the foreground. The likelihood that he might be faced with a costly change to meet a deadline received sympathetic hearing. This was finally resolved in the provisions of Section 1903, from which I am quoting in part:

> Section 1903. The public policy declared . . . [herein] shall be taken into consideration by all agencies of the Federal Government in connection with all procurement and price support programs and operations and after June 30, 1960, no agency or instrumentality of the United States shall contract for or procure any livestock products produced or processed by any slaughterer or processor which in any of its plants or in any plants of any slaughterer or processor with which it is affiliated slaughters or handles in connection with slaughter livestock by any methods other than methods designated and approved by the Secretary of Agriculture . . . . After June 30, 1960, each supplier from which any livestock products are procured by any agency of the Federal Government shall be required by such agency to make such statement of eligibility under this section to supply such livestock products as, if false, will subject the maker thereof to prosecution, section 287 of Title 18.

There is included in this section a provision with respect to any national emergency, and some additional language concerning the affiliation of the slaughterer or processor. The June 30, 1960 date specified in Section 1903 has some of the elements of the effective date of the statute. Actually, however, as soon as the secretary designates a method of slaughter as being humane, industry has an opportunity to satisfy whatever interest in humane slaughter might be current in his area.

As mentioned above, there was considerable interest expressed in kosher slaughter at the hearings. These interests were resolved by the Congress in the following section, which is quoted in part:

> Section 1906. . . . Notwithstanding any other provision of this chapter, in order to protect freedom of religion, ritual slaughter and the handling or other preparation of livestock for ritual slaughter are exempted from the terms of this chapter.

In view of the clear language in Section 1906, it has been decided that no administrative designation as "humane" is necessary for ritual slaughter and the handling or other preparation of livestock for ritual slaughter.

Immediately on approval of the federal humane-slaughter law on August 27, 1958, the Department of Agriculture organized to meet the target date of March 1, 1959. That, as noted previously, was the date identified in the statute as being when the secretary should issue designations of humane methods of slaughter.

The secretary's advisory committee, consisting of 12 members, was selected. This committee is made up of two representatives of national meat-packer organizations, one trade-union representative, one representative of the general public, two representatives of livestock producers, one from the poultry industry, two representing humane societies, one representing the veterinary profession, and one rabbinical representative.

Research and investigation were immediately instituted, and it was decided to examine into devices already available for rendering animals unconscious, to determine their suitability for use under conditions in this country both in terms of humaneness and adaptability to production lines.

Meetings of the advisory committee were held and reports of the results of research and investigation were reviewed exhaustively.

The *Federal Register* for March 3, 1959, at page 1549, contained the published designations of humane-slaughter methods (9 CFR 180). The Code of Federal Regulations covers each approved method in considerable detail. I will merely identify the methods and comment briefly on each.

Mechanical—Captive Bolt.—A number of captive-bolt stunning devices have been made available to industry. These include instruments developed in this country and some imported from Europe. For the most part, the captive bolt is propelled by the discharge of a blank cartridge. There is also on the market a pneumatic tool manufactured in this country. The shape of the impact end of the captive bolts differs somewhat, ranging from a mushroom head which does not penetrate the skull to the penetrating type which, in effect, is merely the blunt end of the bolt. The captive bolt has been demonstrated to work quite effectively on cattle, sheep and calves. The skull structure of swine is such as to make difficult the effective use of the captive bolt on this species. Currently, the captive bolt is quite generally used in connection with cattle slaughter.

—*Gunshot.*—The gunshot method of stunning has been used for some time quite widely and effectively on horses in this country. It is also used by a few cattle slaughterers. Regular rifle ammunition is used, shooting the conventional bullet into the skull. Care, of course, must be exercised to control the free projectile and avoid accidents.

Chemical—Carbon Dioxide.—Equipment using carbon-dioxide gas has been developed that will effectively anesthetize hogs, sheep and

calves prior to bleeding. Although many packers have expressed interest in the use of the carbon-dioxide method, the cost of installation has resulted in a kind of "wait and see" attitude. Several large hog slaughterers have already installed the equipment, and its practical value has been clearly demonstrated. The carbon-dioxide method is also now available for the smaller operator.

Electrical.—The difficulties attending the effective use of captive-bolt stunning of hogs and the cost of installing the carbon-dioxide method have stimulated interest in electrical stunning. Considerable progress has been made in eliminating objectionable conditions that were experienced with the earlier use of electrical stunning on hogs. These conditions involved hemorrhaging into the organs and even the muscle tissue. Attention has been focused on two aspects of the electrical stunning operation. The equipment must be so designed that the electrical charge, after passing through the brain, will be grounded through the stunning equipment and not through the animal to the floor or the restraining equipment. Also, the animal must be bled immediately after stunning.

State Legislation

With the passage of the federal law, proponents of humane-slaughter legislation have focused their attention on the states. In a leaflet entitled *End Needless Cruelty with Nationwide State Humane Slaughter Laws,* the American Humane Association points out that the federal law applies to only a certain percentage of the food animals slaughtered each year in the United States. This is 80 per cent of the commercial slaughter. These few figures serve to complete the picture—the 100 million food animals covered by the federal law are slaughtered in a little more than 500 plants, while the 25 million animals not covered by the federal law are slaughtered in more than 2,500 plants.

As I have indicated earlier, it may be that the public interest aroused in connection with supporting humane-slaughter legislation will turn out to be more effective than the wording of the laws themselves in bringing about a change in slaughtering practices in this country. With the passage of the federal law and the publishing by the Secretary of Agriculture of designated methods of humane slaughter, all 3,000 slaughterers in this country may find it desirable to modify their slaughtering methods in response to expressions of local interest. **[The End]**

Color Additives—

THE SCOPE OF PENDING LEGISLATION

By EDWARD BROWN WILLIAMS

The FDA-Supported Color-Additives Proposal Is Even More Restrictive upon Industry, in Its Field of Application, Than Is the Food-Additives Amendment, According to the Author, Who Addressed the Recent ABA Meeting at Miami Beach

ONE of the most striking aspects of recent food and drug legislation is the manner in which, with relative suddenness, it has brought into the regulatory arena substantial industries which in the past were affected only incidentally, if at all, by government regulation of foods and drugs. The pesticide-chemicals amendment, the food-additives amendment and, in the near future—we may presume—the color-additives amendment reach out to gather under the regulatory tent manufacturing enterprises which not so long ago would have scorned the notion that an agency established to police the Nation's food and drug supply could have anything to do with the regulation of their businesses. Indeed, even after the passage of the pesticide-chemicals amendment and the food-additives amendment it came as a distinct shock to some of the affected group outside the food and drug industries that they had been handed serious legal responsibilities under the new legislation.

The Federal Food, Drug, and Cosmetic Act of 1938, through its new-drug section [1] and its coal-tar-color certification sections,[2] for the first time in United States food and drug law, placed upon manufacturers and shippers of new drugs and coal-tar colors for foods, drugs and cosmetics the legal responsibility for obtaining government clearance of such products before introducing them into interstate commerce.

[1] Sec. 505, 21 USC Sec. 355.

[2] Secs. 406(a), 504, 604, 21 USC Secs. 346(a), 354, 364.

Mr. Williams Is Engaged in the Private Practice of Law with a Washington, D. C. Firm

This departure from the traditional statutory and common-law approach requiring the government to prove its case was perhaps not too startling to coal-tar color manufacturers because most of them had become accustomed to an informal procedure for the listing and certification of coal-tar colors which had been instituted under the Food and Drugs Act of 1906. Manufacturers of new drugs were disturbed at the idea that the government should be granted licensing power over the use of their products but, in general, they have become reconciled to the preuse clearance procedure under the new-drug section of the 1938 Act and, indeed, many have come to favor it because of the protection which it offers both to themselves and the public.

Many pesticide manufacturers and manufacturers of other chemicals have long been conscious of the problem of assuring the safety of fresh produce, bearing or containing chemical residues, and of the liability of such products to regulatory action under the Federal Food, Drug, and Cosmetic Act or the Federal Insecticide, Fungicide, and Rodenticide Act,[3] or both. But only chemicals which are "economic poisons" under the relatively moderate requirements of the Insecticide, Fungicide, and Rodenticide Act have been subjected to preuse clearance procedures as a condition to their legal shipment for use in or on food.

The pesticide-chemicals amendment does not purport to control the labeling of pesticide chemicals sold to growers and shippers of raw agricultural commodities. The labeling of such chemicals is regulated under the Federal Insecticide, Fungicide, and Rodenticide Act.[4]

[3] 7 USC Secs. 135 and following.

[4] The definition of "food" in Sec. 201(f) of the Food, Drug, and Cosmetic Act (21 USC Sec. 321(f)) includes "articles used for components" of food, but apparently this has not been construed to bring pesticide chemicals under the labeling provisions of the Act.

Nevertheless, the impact of the pesticide-chemicals amendment upon chemical manufacturers, shippers of raw agricultural commodities, and suppliers of packaging materials for such commodities has been substantial. They now find it necessary to obtain tolerances for pesticides used on such commodities, or which may migrate to them, before the commodity is shipped in interstate commerce (unless, of course, the chemical used is generally recognized as safe under the conditions of its use, within the meaning of the amendment).

The food-additives amendment represents a far more radical departure from the traditional methods of food regulation than did the pesticide-chemicals amendment. Not only does it shift the burden of proof to industry to show safety of additives and to obtain government clearance before interstate shipment of foods containing additives but, as construed by the Food and Drug Administration, it subjects to the applicable provisions of the Act chemicals destined for use in food or which may reasonably be expected to become components of food and also food-packaging materials containing chemicals which may be expected to come into contact with food, even though actual contact has not occurred.

Thus, an additive manufacturer may be subject to the requirements of the amendment for shipment of an adulterated substance to a food manufacturer or perhaps even to a manufacturer of food-packaging materials. Since the additive is regarded as a food, even though it is not adulterated under the chemical-additives amendment, it or its shipper may be proceeded against in the courts for failure to comply with the labeling requirements of the basic Act. Apparently, under the FDA view, even the manufacturer of components of a chemical which is compounded by another person may be affected by the new law.

The concept of regulation of the safety of foods was therefore extended back to include not only the suppliers of substances not previously regarded as subject to food regulatory action or as foods at all, but to the suppliers of substances intended for use in food-packaging materials, which are decidedly not within the generally accepted meaning of the term "food." The initial impact of the statute is no longer at the "food" level, in the usually understood sense of that term, but at the source of the material which may cause the food to be unsafe.

The proposed color-additives amendment now before Congress, which is supported by FDA, is at once more comprehensive and more

restrictive upon industry, in the field of its application, than is the food-additives amendment.

Scope of Jurisdiction Under Proposed Color-Additives Legislation

The definition of the term "color additive" in H. R. 7624, introduced by Representative Oren Harris, chairman of the Committee on Interstate and Foreign Commerce of the House of Representatives, includes any substance derived from any source which, when added or applied to a food, drug or cosmetic, or to the human body, is capable of imparting color thereto, except substances which the Secretary of the Department of Health, Education, and Welfare determines are used or intended to be used for purposes other than coloring.[5] Thus, there is apparently no limitation upon the scope of the definition as regards substances added or applied to foods, drugs or cosmetics or to the human body for the purpose of imparting color. All such substances are within the reach of the proposed legislation. A bill introduced into the Senate by Senator Lister Hill—S. 2197—contains the same provisions as the House bill, including the definition of "color additive," except that it omits the provision of the House bill dealing specifically with additives which are found to induce cancer.[6]

Even such common and harmless articles as fruit and vegetable juices, and concentrates and extracts of such juices, appear to be comprehended within the term "color additive" as so defined, as are other concededly safe substances, including those proposed by FDA for exemption from the food-additives amendment, on the ground that they are generally recognized as safe for use in foods. The FDA exemption proposal, which was published in the *Federal Register* for December 9, 1958, listed the following colors: caramel, carbon black, charcoal, titanium dioxide and ultramarine blue. Some other natural colors which may fit into the same category are chlorophyll, xanthophyll, saffron and annatto.

Strange as it may seem, it would be possible under the proposed legislation for FDA to require the payment of fees for the listing of such colors (Section 706(e) of the Act, as amended by the bills).

When substances in this category are used to impart color to foods they would be subject to the procedural requirements for FDA

[5] For convenience, the authority and responsibilities which the proposed legislation entrusts to the Secretary are hereinafter treated as those of the Food and Drug Administration.

[6] Sec. 706(b)(5)(B) of the Act as amended by H. R. 7624.

clearance applicable to other colors with respect to which there may be no clear and adequate evidence of safety, despite the fact that they have been proposed by FDA for exemption from the food-additives amendment.

It is true that colors which are known to be harmless and have been used commercially prior to the enactment date would be deemed to be provisionally listed for the prior uses and would, *as to such uses,* be deemed exempt from certification requirements (Section 203(a)(2) of the bills). This seems to mean that a concededly safe color used in a particular food prior to the enactment date of the proposed law would be deemed to be provisionally listed and exempted from certification for use only in the particular food in which it was used prior to the enactment date and, presumably, only in the quantities in which it was used in such food. If occasion arises for its use in a different quantity or in another food, the color would be deemed unsafe unless its use were certified or exempted from certification for such use by a certification regulation (Sections 706(a), (b) and (c) of the Act, as amended by the bills).

A formal petition under Section 701 of the Act would be required to obtain a listing, and exemption from certification, of any new use of such a color unless FDA should act upon its own initiative as provided in Section 701.[7] In any event, a regulation would have to issue, listing and exempting the particular use from certification, before the end of any period of provisional listing and exemption from certification; a proposal for listing would have to be published; and any interested person would have an opportunity to object. If there is any objection by a person adversely affected, the regulation would be stayed and a public hearing would be held; perhaps an appeal to the courts would follow. The person "proposing" the use—who, in fact, may have been using the color for many years—must anticipate that, through these procedures, a competitor may bring about costly delays, litigation, and even an eventual denial of the use of the color.

Paprika and turmeric are used in certain frozen foods as condiments, yet, since they impart color, they would be subject to the color-additives amendment and the listing and certification procedures unless they could be exempted upon the ground that they are used solely for purposes other than coloring, as provided in the definition of "color additive." It is by no means certain that such an exemption

[7] 21 USC Sec. 371.

could be obtained. Whether or not such an exemption could be obtained, it is pertinent to inquire what public-health purpose is served by requiring that persons using such substances be subjected to harassment of the legal procedures which would be necessary to obtain either a listing or an exemption.

Even colors permitted by definitions and standards of identity would be subject to the clearance procedures.

It would not be a very satisfying answer to the objections which have been made to the scope of the color bills to say that concededly safe colors will be cleared without difficulty for listing and exemption from certification. The hazards inherent in the procedures which must be followed to achieve clearance do not lend assurance that this result will follow as a matter of course. Some of these hazards have been indicated. There are others. Important among them is the provision extending the preclearance principle to colors whose use FDA thinks will result in economic adulteration or misbranding of the product for which they are proposed as ingredients.

Misbranding and Adulteration by Use of Color

FDA would be directed under the proposed legislation not to list an additive for a proposed use if the data before it showed that such use would promote deception of the consumer in violation of the Act or would otherwise result in misbranding or adulteration (Section 706(a)(6) of the Act as amended by the bills). Here is a clear enough indication that the listing of concededly safe colors will not follow as a matter of course and that each use of a color will be scrutinized by FDA to determine whether it appears to be in conflict with any provision of the Act other than the color-additives amendment or whether it would "promote deception of the consumer in violation of the Act," whatever that generalized catchall may mean.

If FDA refuses to list a color under this provision, the remedy of the manufacturer or shipper of the color is to appeal to the appropriate United States Court of Appeals under Section 701 of the Act, after following the procedures for objection and hearing provided under that section. In such a judicial proceeding, the findings of FDA as to the facts are conclusive upon the court if based upon a fair evaluation of the entire record of the administrative hearing. Thus, the burden of proof which, under the basic structure of the statute, has heretofore been upon the government in the enforcement of the adulteration and misbranding provisions of the Act, would effectively be

shifted from FDA to the person who proposed to use the additive. The substance cannot be used until FDA or the court is convinced that it will not misbrand or adulterate the food in which it is proposed for use. FDA would no longer have to adduce proof of violation by a preponderance of the evidence. In practice, opinion evidence of FDA experts may be expected to play a substantial role in such cases. Here, then, is an effective extension of the licensing system to substantial areas of economic adulteration and misbranding of foods, drugs and cosmetics coupled with a significant lightening of the requirement of proof by the government.

A similar provision is, of course, found in the food-additives amendment (Section 409(c)(3)(B) of the Act). It does not appear to be germane either to food-additives legislation or color-additives legislation, which is designed fundamentally to assure the safety of those additives. It is demonstrably more objectionable, however, in the proposed color legislation than in the food-additives amendment.[8]

Failure of Proposed Legislation to Provide Reasonable Test of Coverage

The burdensome character of the procedural requirements of the proposed legislation is not relieved by any practical jurisdictional test which would exclude from the statute colors known to be harmless nor is there any authorization for an exemption from the procedural requirements for the listing of such articles.

The food-additives amendment contains a jurisdictional provision, elusive in meaning as it is, which is patterned upon that of the new-drug section of the Act: The test of general recognition of safety by qualified experts. If a substance is generally recognized as safe under that test, it is not subject to the food-additives amendment. This is a troublesome and unrealistic approach to the determination of coverage but it would have, at least, the merit of excluding from the proposed color legislation substances known to be harmless, such as natural coloring materials, including those which have been proposed for exemption from the food-additives amendment by FDA.

It seems unreasonable to require that additives known to be safe be cleared under legislation of this kind. If a color is safe and not subject to regulation under the food-additives amendment, what justification is there for its regulation under color-additives legislation?

[8] Similarly objectionable is Sec. 706(s)(7) of the Act, as amended by the bills, which authorizes denial of the use of additives which will not, according to the data before FDA, "achieve the intended physical or other technical effect."

Evidentiary Test of Coverage

The same approach would appear to be sensible in dealing with colors not so well known but with respect to which the manufacturer or shipper has accumulated evidence of safety which qualified experts would, upon examination, consider to be adequate, regardless of whether there was general recognition of safety.

Before the enactment of the food-additives amendment, I noted that a realistic evidentiary standard for testing the jurisdiction of FDA under that amendment was desirable and practicable.[9] In certain types of civil cases the standard of proof applied by the courts requires that, for a party to prevail, he must establish his case by "clear and convincing" evidence—a showing which is plain and convincing beyond reasonable controversy. This test could be applied to color-additives legislation and food-additives legislation as a basis for determining whether a color additive is safe for use and not subject to the requirements of the proposed legislation, including both listing and certification of batches.

Thus, the definition of the term "color additive" could reasonably be limited by excluding from that term (1) colors which are generally recognized by qualified experts as safe for use under the intended conditions of use (the test of coverage adopted in the food-additives amendment) and (2) colors with respect to which there is clear and convincing evidence derived from scientific procedures or from common use and acceptance of such colors in food, or from both, that the use of such colors under the intended conditions of use will offer no reasonable possibility of hazard to the public health. Under such a jurisdictional test, a color would be excluded from the definition of "color additive" if it could be shown by clear and convincing evidence that it had been adequately tested to demonstrate its safety. Natural substances used for coloring and other substances known to be safe would be excluded under the general-recognition portion of the proposed definition. Others with respect to which evidence of safety was available would be excepted from coverage if such evidence was clear and convincing that their use would offer no reasonable possibility of hazard to health. There appears to be no reason why a test of this nature could not be devised for application both to the listing and certification provisions of the pending bills.

[9] "The Food Additive Matter—Comments on Proposed Legislation," 12 *Food Drug Cosmetic Law Journal* 553-557 (September, 1957).

Under such a provision, if the government should bring a legal proceeding against the use of a color, alleging that it was an unlisted additive, it would prevail unless the court were persuaded by clear and convincing evidence that the additive was safe or that it was generally recognized as such by qualified experts.

In such a situation it is difficult to see any justification for subjecting industry to the clearance procedures of the proposed legislation. In practice, FDA ordinarily would be invited to express an opinion as to whether there was clear and convincing evidence, or general recognition, of safety. If the person proposing to use the additive should disagree with the opinion of FDA, he could decide upon a course of action with the knowledge that, in the last analysis, the question of coverage would be determined upon the basis of a workable evidentiary test.

It is not my wish to labor this point unnecessarily, but I am apprehensive that the difficulties which will be encountered in clearing substances which, as a practical matter, require no clearance to show their safety are going to place an entirely unjustified burden of time and expense upon the industries affected—in particular, the food industry. If there were any necessity for such clearances to assure safety, the requirements of the bill with respect to such colors would be understandable. But I know of no such justification.

FDA Position

It was stated in the "Explanation of Principal Features and Purposes of Proposed Color Additive Amendments of 1959," submitted to Congress by the Department of Health, Education, and Welfare, with a draft of a proposed color-additives bill:

> While there may have been justification in the case of the Food Additives Amendment of 1958 for placing the burden on the government to prove that an additive is *not* generally recognized as safe before the safety clearance procedure applies—in view of the broad sweep of the amendment, which otherwise would have covered such additives as salt, vinegar, and natural spices—we do not believe that such an exception is sound in the case of color additives, whether they be extracted from a natural source or synthesized.

If it made sense to exclude from the color-additives amendment such additives as salt, vinegar, and spices and other substances known to be safe, it likewise makes sense to exclude from color-additives legislation substances known to be safe. With respect to such substances, there can obviously be no question of imposing a burden of proof upon the government, since their safety is conceded. With

respect to other substances, this burden is, as is well known, largely illusory, since there will rarely be any disposition on the part of industry to resort to a court proceeding to prove general recognition of safety. If FDA cannot be convinced that an article is generally recognized as safe in the usual case, the matter will end right there.

The situation would be somewhat similar if the "clear and convincing evidence" test which has been suggested were adopted by Congress. If the evidence did not convince FDA of safety, industry would ordinarily proceed to comply with FDA demands for formal clearance and submission of additional data. But, at least, a member of industry who was convinced of the soundness of his position would have an opportunity to invoke judicial consideration of it upon the basis of a concrete evidentiary test rather than be compelled to rely solely on the ephemeral "general recognition" doctrine, under which, as it is administratively interpreted, no truly new product can be exempted from coverage.

It is the position of the Food and Drug Administration that, from the point of view of determining safety of use, there is no sound scientific basis for distinguishing between a color additive extracted from a plant, animal or mineral source and one which is synthesized with a chemical structure which classifies it as a coal-tar color. Consequently, it is said, the proposed legislation was drafted to apply to all color additives whether or not they are coal-tar colors.[10]

If, however, safety of use is the criterion for coverage, it requires more perception than some of us possess in order to understand why substances which FDA and the scientific community know to be safe —and which are therefore exempted from the food-additives amendment—should be subject to color-additives legislation.

It has long been assumed that, to assure their safety, many coal-tar colors used in food, drugs and cosmetics require special treatment by way of batch certification. We may accept that proposition which boasts of long historical precedent and yet maintain consistently that colors other than those coal-tar colors which require batch certification should be dealt with like other additives. If batch certification is not necessary for additives other than color additives, it is not apparent why it should be required for color additives (again, granting the exception for coal-tar colors). Surely, in the case of foods, color addi-

[10] "Explanation of Principal Features and Purposes of Proposed Color Additive Amendments of 1959" (submitted to Congress by the Department of Health, Education, and Welfare with a draft of a proposed color-additives bill), p. 2.

tives from mineral, plant or animal sources offer no greater hazard to the public health than the vast numbers of other additives from such sources which are used in foods. Such additives would be adequately controlled by the food-additives amendment. The fact that colors used in drugs and cosmetics are not regulated by that amendment furnishes in itself no basis for treating colors used in foods in a different manner from that in which other food additives are treated.

Cancer Provision

The color-additive bill pending in the House of Representatives (H. R. 7624) like the food-additives amendment, contains a provision prohibiting the listing of an additive "if the additive is found to induce cancer when ingested by man or animal." (Section 706(a)(5)(8) of the act as amended by the bill.)

Under both the food-additives amendment and the color-additive bill as introduced in the House, the quoted clause incorporates the definition of the term "additive." [11] Consequently, in the case of the food-additives amendment, the language in question, it seems to me, can logically mean only that use of the additive is prohibited "if it—i.e., the substance not generally recognized as safe under the conditions of its intended use—is found to induce cancer when ingested by man or animal." The test of "conditions of its intended use" is the basis for determining the applicability of the amendment. As a matter of statutory construction, therefore, the applicability of the cancer clause depends upon a finding that, under the conditions of its intended use, the additive induces cancer when ingested by man or animal. This construction is the only one which comports with the recorded legislative history of the cancer clause. Thus, Representative Harris, who was in charge of the bill, said in the House of Representatives:

> While the [Interstate and Foreign Commerce] Committee felt that the bill as reported by the Committee includes the matter covered by the Delaney amendment [the cancer clause] in the general language contained in the bill, there was no objection to the addition of the amendment suggested by Mr. Delaney . . . .[12]

The report of the Senate Committee on labor and public welfare declared:

> We want the record to show that in our opinion the bill is aimed at preventing the addition to the food our people eat of any substances which reasonable

[11] The pertinent portion of the food-additives amendment reads: "If it is found to induce cancer when ingested by man or animal" (Sec. 409(c)(3)(A)). The antecedent of "it" is, however, the term "food additive," previously used in the same subclause (A).

[12] *Legislative Record of 1958 Food Additive Amendment* (Food Law Institute Series, Commerce Clearing House, Inc.), pp. 38-39.

people would expect to produce not just cancer but any disease or disability. In short, we believe, the bill reads and means the same with or without the inclusion of the clause referred to. This is also the view of the Food and Drug Administration.[13]

Obviously, the view of the Food and Drug Administration changed subsequent to the enactment of the food-additives amendment. The Administration now maintains that any additive which has been found to induce cancer by ingestion is deemed to be unsafe regardless of whether or not it is perfectly safe in the quantities used and under the other conditions of its use. For the reasons stated, this appears to be an unnecessarily restricted interpretation of the statutes, but we have seen in experience that it is one with which industry must reckon.

If, however, the cancer provision were included in a color-additives amendment, it would be difficult to quarrel with such a construction. There is no test of coverage such as that under the food-additives amendment, which excludes from the term "color additive" substances generally recognized as safe under the conditions of their intended use. Consequently, the provision in question would obviously deny clearance to any color found to induce cancer in man or animal, without regard to the particular conditions of its use or intended use.

It would hardly be safe to anticipate that any legislative history would develop which would have the effect of modifying such an interpretation of the cancer provision proposed for color-additives legislation. As matters now stand, a collateral effect would doubtless be confirmation of the FDA interpretation of the corresponding provision in the food-additives amendment.

Conclusion

It was recently reported in a well-known trade publication [14] that, according to a "highly placed" FDA official, color-additives legislation will have to be sought by industry on a "pig-in-a-poke" basis and that the alternative of remaining under the existing coal-tar color law could mean that industry has a colorless future.

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[13] S. Rept. 2422, 85th Cong., 2d Sess., pp. 11. It seems possible to give substantial effect to the clear intent of the Senate Committee without reading Sec. 409(c)(3)(A) and its cancer proviso as requiring application of the same criteria of safety to substances which are "found to induce cancer" as must be applied to other substances. Thus, a "fair evaluation" of the data before FDA relating to substances "found to induce cancer" on the basis of animal experiments may well permit the application of stricter standards than in other cases, thereby giving effect to the cancer proviso. The clause might, in fact, be read as excepting such substances from the basic requirement of a "fair evaluation" of the data before FDA, which is set forth in Sec. 409(c)(3)(A).

[14] *FDC Reports*, August 10, 1959, p. 11.

In view of the apparent intensification of suspicions and opinions that a number of coal-tar colors may be carcinogens, the unclear image of the beast in the bag may become less and less alluring to those members of industry who have been affected by FDA's per-se interpretation of the existing coal-tar color provisions of the statute, for any coal-tar color which is found to induce cancer in man or animal would be outlawed under the per-se language of the cancer amendment.

Even without the cancer provision we can tell from the preceding discussion of the scope of the pending bills that the porker in the bag is a troublesome and even a mean creature. The situation is the more discomforting because there is no apparent public-health basis for the extremely broad jurisdiction which is sought in the Administration-supported bills. **[The End]**

• CRANBERRY STORY: COOPERATION •

On November 9, Secretary of Health, Education, and Welfare Arthur S. Flemming released a statement at a Washington, D. C. news conference to the effect that the Food and Drug Administration was urging that no further sales be made of cranberries and cranberry products originating in Washington and Oregon in 1958 and 1959, pending the separation of berries which might have been contaminated by aminotriazole, a chemical weed killer, from berries not so contaminated. According to the statement, the Administration had discovered contamination of some of the 1959 northwestern crop and was undertaking a check of the 1958 crop, and the Administration was seeking to determine whether any other crops were contaminated. The Secretary noted that over 3 million pounds of cranberries from the 1957 northwestern crop and a small amount from the 1957 Massachusetts crop were currently being destroyed—voluntarily by the national cranberry association—because of contamination by the weed killer. He explained that aminotriazole has been found to induce cancer when fed to rats; no tolerance has been established for its residues in or on agricultural commodities.

On November 10, FDA issued a statement that samples of cranberries and canned cranberry products were being collected for analyses from producing areas by inspectors of FDA's 17 district offices. The Administration also announced that investigations were under way in producing areas to determine the extent and manner of use of aminotriazole.

Just nine days later—November 19, 1959—Secretary Flemming announced a satisfactory certification plan worked out by FDA and representatives of the cranberry industry. He outlined procedure, stating:

"The outstanding features of this plan can be summarized as follows:

"1. It assures proper testing of fresh cranberries and processed cranberry products in all stages of marketing—wholesale and retail—before they are offered to the consuming public;

"2. It provides for approved labels which the housewife can look for to be sure the package, can or bottle she buys is from a tested lot containing no aminotriazole.

"Misuse of approved statements would be a criminal offense under the Federal Food, Drug, and Cosmetic Act."

By ARTHUR T. SCHRAMM

Color Additives—Proposed

The Manager of Field Sales, National Aniline Division, Allied Chemical Corporation, Discusses the Color-Additives Problem Involving the Word "Harmless." His Article Is Derived from a Speech Which He Delivered at the Annual Meeting of ABA's Food, Drug and Cosmetic Law Division, at Miami Beach on August 24

FOOD COLORS first came to the attention of lawmakers at the turn of the century. Coloring of food had been practiced for centuries, the coloring matter used having been natural in origin—animal, vegetable or mineral. The discovery of dye synthesis in 1856 led to the production of synthetic dyes which were quickly demonstrated to be superior in uniformity, tinctorial value and application properties. Since some of the manufacturers of synthetic dyes, at that time, were unaware of their use in food, many batches of these dyes were found to be contaminated with lead, arsenic, and other substances rendering them unsuitable for such use. This situation produced a public-health hazard which was recognized early in 1900 and acted upon legally in 1906 with the passage of the Federal Food and Drugs Act. Regulations issued under this Act restricted the synthetic coal-tar colors used in food to seven in number and made provision for future additions of other acceptable dyes to the list. The list grew to 19 in 1950 with the addition of FD&C Violet No. 1 by Allied Chemical Corporation's National Aniline Division.

Establishment of Certification Procedure

Regulations promulgated under the Federal Food and Drugs Act of 1906 effected the elimination of undesirable contamination from dyes used in food as responsible manufacturers, submitting to control, voluntarily forwarded each batch of dye to Washington for certification of absence of impurities. In 1938, the Federal Food, Drug, and Cosmetic Act made this certification procedure mandatory and animal-

Amendments

testing data were supplied to support continued listing of specified colors under the new Act. Regulations established under this law designated colors permitted for use in food, drugs and cosmetics as FD&C colors; in drugs and cosmetics only as D&C colors; and in externally applied drugs and cosmetics as Ext D&C colors.

In September of last year, the food-additives amendment was enacted to give the Food and Drug Administration authority to control the use of food additives under safe conditions. The amendment excludes from its provisions "any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to this Act . . . ." [1] Among the food additives thus excluded are the so-called "coal-tar colors," use of which has been authorized under Section 406(b) of the Federal Food, Drug, and Cosmetic Act of 1938, which reads as follows:

> The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents.[2]

Regulations established under this section include the following requirements:

> (a) An application for the admission of a coal-tar color to listing in section 9.3, 9.4, or 9.5 shall be accompanied by—
>
> (1) full reports of investigations which are adequate to show whether or not such color is harmless and suitable for use in food, drugs, and cosmetics, or in drugs and cosmetics, or in externally applied drugs and cosmetics, as the case may be;

[1] 72 Stat. 1784, 21 USCA Sec. 321(s)(3) (Supp., 1958).

[2] 52 Stat. 1049 (1938), 21 USCA Sec. 346 (b) (Supp., 1958).

(2) a full statement of the percentages and compositions of the pure dye and all intermediates and other impurities contained in such color;

(3) a full statement showing the identity, purity, and quantity or proportion of each intermediate and other article used as a component of such color, and all steps in the process used for the manufacture of such color;

(4) a full description of practical and accurate methods of analysis for the quantitative determination of the pure dye and of all intermediates and other impurities contained in such color;

(5) a full description of practical and accurate methods for the identification of such dye in food, drugs, and cosmetics colored therewith, or in drugs and cosmetics colored therewith;

(6) a five-pound sample of such color (unless the Food and Drug Administration authorizes or requires submission of other quantity suitable to the need for investigation) taken from a batch produced under practical manufacturing conditions, and accurately representative of such batch; and

(7) the advance deposit prescribed by section 9.15(b)(2).

Similarity of Color-Additives Conditions to Those Required for Approval of Food Additives

It should be noted that these conditions for addition of a new color to the permitted list are similar to those now required for approval of a food additive under the new amendment (see Section 409(b)). The food colors were listed in 1938 upon presentation of extensive animal testing data, including lengthy feeding studies to evaluate potentiality for chronic toxicity. This is mentioned to emphasize the fact that the existing requirements for food colors are comparable in this respect with those of the food-additives amendment except for one detail: The latter requires data bearing on the quantity of additive needed to produce the intended effect whereas the former fails to take cognizance of quantity.

Sections 504[3] and 604[4] of the 1938 Act give the Secretary authority over colors to be used in drugs and cosmetics, which, of course, are not included under the food-additives amendment. Color additives not regarded as coal-tar colors presumably are subject to the provisions of that amendment.

Colors Delisted

In recent years the Food and Drug Administration has issued orders delisting FD&C Orange Nos. 1 and 2, FD&C Red No. 32 and FD&C Yellow Nos. 1, 2, 3 and 4, and proposed to delist 17 D&C colors. These actions on the part of FDA are based on the contention

[3] 52 Stat. 1052 (1938), 21 USCA Sec. 354 (Supp., 1958).

[4] 52 Stat. 1055 (1938), 21 USCA Sec. 364 (Supp., 1958).

that these colors are not "harmless" and, hence, not suitable for use because they produced adverse physiological effects in test animals when fed at very high levels for long periods of time. The fact that the quantities fed were unrelated to, and far in excess of, amounts ingested by humans has been disregarded because FDA defines the word "harmless" in Section 406(b) as meaning incapable of producing any harm in any quantity under any circumstances. In other words, the entire color-additive problem involves the definition of the word "harmless," and a decision of the United States Supreme Court on December 15, 1958,[5] supports FDA's view in this matter. It should be noted, therefore, that this problem is in reality a legal one and the erroneous impression that food, drug and cosmetic colors constitute a threat to public health has resulted from misleading statements appearing in sensationalistic journals deliberately designed to catch the public eye.

Realizing that implementation of this interpretation would lead to delisting of practically all colors, a result it did not desire, the Department of Health, Education, and Welfare effected the introduction this year of proposed remedial legislation: H. R. 7624, by Mr. Oren Harris, and S. 2197,[6] by Senator Lister Hill—identical bills except for Section 706(b)(5)(B), which occurs in the House bill but not in its Senate counterpart.

Cooperation of Certified Color Industry Committee

The Certified Color Industry Committee has worked very closely with the Department and FDA in seeking this much-needed legislation, the first step having been the introduction of H. R. 8945[7] in the House of Representatives by Congressman Thomas B. Curtis during the Eighty-fifth Session of Congress. Comments on this bill, submitted by Mr. Elliott L. Richardson, assistant secretary, to Mr. Oren Harris, chairman of the House Committee on Interstate and Foreign Commerce, may be summarized by quoting Mr. Richardson's own conclusion:

> While we cannot support the bill, and especially the grandfather clause, in its present form, we favor the basic principles of the bill and would favor its enactment if modified along the above-suggested lines. We should be glad to submit such technical and other assistance to that end as the Committee may desire.

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[5] *Flemming v. Florida Citrus Exchange*, CCH Food Drug Cosmetic Law Reports ¶ 7468, 358 U. S. 153 (1958); See Becker, "Courts and Food Colors," 14 *Food Drug Cosmetic Law Journal* 330 (May, 1959).

[6] 86th Cong., 1st Sess. (1959).

[7] 85th Cong., 1st Sess. (1957).

In subsequent meetings between repesentatives of various industries and government personnel, most of the differences were resolved and the two bills were introduced.

The Certified Color Industry Committee, having recognized the urgent need for legislation in the interest of all concerned—FDA, manufacturers and consumers—and having given careful consideration to the provisions of H. R. 7624 and S. 2197, thoroughly approves the basic principles involved. It is believed that these bills, in general, are well designed to accomplish their purpose, namely, to authorize the safe use of suitable color additives. As a matter of fact, the committee has registered objections to only two provisions: Section 706(b)(4)(C)(ii), at page 9, lines 12-16, in both bills and Section 706(b)(5)(B), at page 10, lines 11-22, in the House bill only.

Section 706(b)(4)(C)(ii)

Section 706(b)(4)(C)(ii) would prohibit the Secretary of Health, Education, and Welfare from the very listing of a color unless the data before him would establish "that practicable methods exist for determining the identity and quantity . . . of any substance formed in or on such article (of food, drug or cosmetic) because of the use of such additive." Subdivision 4(A) of the same section requires that the data establish "that such use, under the conditions of use to be specified in the regulations, will be safe." We believe that subdivision (4)(C)(ii) not only fails to add anything to the safety requirements of (4)(A) but rather introduces an unreasonable requirement that could prevent the use of a color additive on an article because such use might form a substance, which, although shown to be safe under (4)(A), nevertheless could not be identified or measured by practicable methods of analysis. We do agree, however, where use of an additive is *known* to cause the formation of a breakdown or interaction product which may have harmful effects not detected by the data establishing safety under subdivision (4)(A), that practicable methods must be provided for determining identity and quantity of such product. As the provision now reads, it might be interpreted in the future in such a way as to prohibit, on wholly theoretical grounds, the use of color additives which have been found to be entirely safe under the proposed conditions of use. The committee contends that the Secretary's authority in this area should be discretionary rather than mandatory.

Furthermore, this specific prohibition has no counterpart in the 1958 amendment nor the 1954 pesticide provision[8] which provides for the establishment of tolerances and after which the present bill is modeled. The pesticide amendment, which deals with substances with far greater potential for harm than colors, does not have a comparable prohibition. That Act requires as a condition for listing the general one of protecting the public health[9] and does not require that practicable methods exist for determining substances formed on raw agricultural commodities because of the use of such pesticides. Similarly, the recent food-additives amendment does not prohibit the issuance of regulations for use of a food additive despite the absence of practicable methods for determining the quantity of any substance formed in or on food because of the use of such additives. Here, again, the governing criterion is the general concept of safety, and that Act merely provides that a petition proposing issuance of a regulation shall contain, among other requirements, a description of such practicable methods.[10] In other words, discretionary authority is implied.

Resolution of Objection—Industry-HEW Discussions

The foregoing objection has been resolved in the Senate bill as a result of discussions between representatives of industry and the Department. During those discussions it was revealed that mandatory requirements for analytical methods specified in Section 706(b)(4)(B) and (C)(i) would likewise not be applicable in all cases. Hence, it was decided to remove the mandatory requirements for analytical methods as a condition for listing a color additive and, instead, to require such methods only where needed to determine the safety for use of the color additive. This provides desirable administrative flexibility and makes it possible to avoid what could be unnecessary, cumbersome and, sometimes, impossible requirements without concomitant benefit to public health. The following proposed language would replace that which now begins at line 3 on page 9 and ends at line 9 on page 10:

(4) The Secretary shall not list a color additive under this section for a proposed use unless the data before him established that such use, under the conditions of use to be specified in the regulations, will be safe.

(5) In determining, for the purposes of this section, whether a proposed use of a color additive is safe, the Secretary shall consider, among other relevant factors—

[8] Act of July 22, 1954, Ch. 559, 68 Stat. 511 (codified in scattered sections of 21 USCA, Supp.).

[9] 68 Stat. 511 (1954), 21 USCA Sec. 346a (b).

[10] 72 Stat. 1785, 21 USCA Sec. 348(b)(2)(D) (Supp., 1958).

(A) the probable consumption of, or other relevant exposure from the additive and of any substance formed in or on food, drugs, or cosmetics because of the use of the additive;

(B) the cumulative effect, if any, of such additive in the diet of man or animals, taking into account the same or any chemically or pharmacologically related substance or substances in such diet;

(C) safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of color additives for the use or uses for which the additive is proposed to be listed, are generally recognized as appropriate for the use of animal experimentation data; and

(D) the availability of any needed practicable methods of analysis for determining the identity and quantity of (i) the pure dye and all intermediates and other impurities contained in such color additive, (ii) such additive in or on any article of food, drug, or cosmetic, and (iii) any substance formed in or on such article because of the use of such additive.

With this change the committee supports the bill.

Section 706(b)(5)(B)

The second proposed provision with which the committee takes issue is subsection (b)(5)(B) in H. R. 7624:

A color additive (i) shall be deemed unsafe, and shall not be listed, for any use which will or may result in ingestion of all or part of such additive, if the additive is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal, and (ii) shall be deemed unsafe, and shall not be listed, for any use which will not result in ingestion of any part of such additive if, after tests which are appropriate for the evaluation of the safety of additives for such use, or after other relevant exposure of man or animal to such additive, it is found to induce cancer in man or animal.

The committee feels that this specific reference to cancer has no proper place in the proposed legislation. Such provisions add nothing to the basic safety requirement of subdivision (4)(A) that:

. . . the Secretary shall not list a color additive for a proposed use unless the data before him establish that such use, under the conditions of use to be specified in the regulations, will be safe.

Further, from the standpoint of safety and toxicity there is no logical reason for separate mention of cancer as distinguished from other diseases or other adverse physiological effects. As a matter of fact, subdivision (5)(B) would reinstate the outmoded per-se doctrine and reject, insofar as cancer is concerned, the realistic and scientific test of safety under conditions of intended use.

"Color Additive"—Committee-Endorsed Definition

The committee endorses the following definition of "color additive" proposed in H. R. 7624 and S. 2197:

> The term "color additive" means a material which—
>
> (A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and
>
> (B) when added or applied to a food, drug, or cosmetic, or the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;
>
> except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

This definition should be compared with that in effect under the coal-tar color regulations since 1939, which reads as follows:[11]

> The term "coal-tar" color means articles which (1) are composed of or contain any substance derived from coal-tar, or any substance so related in its chemical structure to a constituent of coal-tar as to be capable of derivation from such constituent; and (2) when added or applied to a food, drug, cosmetic, or the human body or any part thereof, are capable (alone or through reaction with other substance) of imparting color thereto.

Extension of Proposed Definition's Scope

It should be noted that the effect of the proposed definition is to extend its scope beyond "coal-tar colors" in such manner as to include all coloring matter used in food, drugs or cosmetics, regardless of source. Actually, the definition now in the regulations has been interpreted by FDA in its broadest sense. This led to a proposal issued in the *Federal Register* January 24, 1957, to amend the definition specifically exempting products normally regarded as natural colors but retaining their synthetic counterparts.[12] A prolonged hearing was conducted on the subject and the final decision has not yet been made.

The Certified Color Industry Committee has taken the view that regulation of the use of color additives in food, as well as in drugs and cosmetics, should make no distinction upon basis of origin, but that all colors, synthetic or natural, should be subject to the same criteria of evaluation. The present definition of "coal-tar color," adopted in 1939, has been interpreted and applied over the years by FDA to include not only color additives derived from coal tar, but in certain cases color additives of natural origin. This has been illustrated by the inclusion of Indigo (D&C Blue No. 6) and Alizarine (D&C Orange No. 15), both natural colors having synthetic counterparts, in the

[11] 21 CFR Sec. 9.1(a).

[12] 22 *Federal Register* 477 (1957).

present list of certifiable colors [13] as well as by the Commissioner's order of June 7, 1957, amending the definition to exclude therefrom certain other colors derived from natural sources.[14] With respect to synthetic colors, such as the beta carotene at issue in the hearing referred to, the committee does not believe that some synthetic colors should be excluded from the definition while others would presumably remain subject to listing requirements merely on the basis of a relationship of the excluded colors to their natural counterparts and without regard to toxicity or other factors. Again, the committee believes that all color additives—natural, synthetic, or synthesized naturally occurring colors—should be subject to the same tests for safety, and it points to the fact, known to all, that mere existence in nature is no guarantee of safety.

It should be mentioned here that the term "coal-tar colors" was originally applied to this group of synthetic food colors because they were derived from substances obtained from coal tar. A disturbing amount of recent unfavorable publicity has been due merely to the association of food colors with coal tar. The popular conception of coal tar, of course, is a thick, black, sticky substance, and the very idea of associating such material with food is understandably repugnant. The fact is, however, that the starting materials obtained from coal tar are isolated and purified to an extremely exacting degree prior to use in synthesis of food colors. The food colors themselves are specific chemical entities totally unrelated to the products from which they are derived and undeserving of the stigma of association with coal tar per se. It is also true that identical starting materials could be obtained from other sources—for example, petroleum.

Important Fundamental Agreement Between Industry and FDA

It is my firm belief that enactment of the bill, modified in the manner described above, would afford full protection of public health and, at the same time, permit the continued use of color additives on a stable and realistic basis. In this connection, it should be noted that despite the controversial situations that FDA and the certified color industry have faced, consistently amiable relations continue to exist and there is full agreement on certain fundamentals, namely, protection of the public health; the necessity for use of color in food, drugs and cosmetics; and the need for prompt remedial legislation.

[The End]

[13] 21 CFR Sec. 9.4(a).

[14] 21 CFR Sec. 9.1 (Supp., 1958).

By PAUL R. DOHL

At the 1959 Meeting, Division of Food, Drug and Cosmetic Law, ABA, at Miami Beach, the Secretary and General Counsel of The Norwich Pharmacal Company, Norwich, New York, Spoke on

Color Additives—Their Regulation

PHARMACEUTICAL manufacturers may aptly be classified as the "orphan children of color regulation" since among industries coming within the purview of the Federal Food, Drug, and Cosmetic Act, producers of cosmetics and food products are by far the largest users of color additives. Nevertheless, colors are used in a variety of ways in the compounding of pharmaceuticals, and their use is extremely important. Consequently, drug manufacturers have a major stake in color legislation.

The history of the regulation of colors in the United States was, until recently, unspectacular. The Food and Drugs Act of 1906 permitted the use of many so-called "coal-tar colors" and authorized augmentation of the list by the addition of supplementary colors.[1] New colors were added routinely over the succeeding years until 1950, when FD&C Violet No. 1 was nominated for certification by the Food and Drug Administration. Despite the fact that Violet No. 1 had been shown to produce adverse pharmacological effects in laboratory animals, the color was nevertheless certified, and the findings of fact in the order stated:

> The amount of color fed the animals in the test referred to was far in excess of the amount that any human might obtain as a result of food colored with F. D. & C. Violet No. 1.

Following the Delaney Committee investigation in 1950 and a review of certified colors by the Food and Drug Administration, Orange No. 1, Orange No. 2 and Red No. 32 were delisted as FD&C colors by an order effective February 14, 1956;[2] the colors were re-

[1] June 30, 1906, Ch. 3915, 34 Stat. 768-772, 21 USC Secs. 1 and following.

[2] 20 *Federal Register* 8492 (November 16, 1955).

listed as certifiable for external drug and cosmetic use only. This delisting order was based upon a finding by the Administration that the three involved colors were not "harmless."

Section 406(b) of the Federal Food, Drug, and Cosmetic Law[3] provides that the Secretary of Health, Education, and Welfare shall promulgate regulations providing for the listing of coal-tar colors which are *harmless* and suitable for use in food and for the certification of batches of such colors with or without *harmless* diluents.

"Harmless"—Relative or Absolute Sense?

Following the 1956 delisting order, the question of whether the word "harmless" as used in the statute should be construed in a relative or absolute sense became a major one. If it were contended that, in enacting Section 406(b), Congress adopted an absolute requirement of harmlessness, no color would be eligible for certification if it produced deleterious physiological effects in laboratory animals notwithstanding the fact that such deleterious effects may have occurred only upon the administration of extraordinary amounts of the color. If, on the other hand, Congress used the word "harmless" in a relative sense, such factors as dosage, route of administration, length of administration and tolerances become important.

Petitions challenging the delisting order were presented under Section 701(f) of the Act in the United States Courts of Appeal for the Second, Fifth and Seventh Circuits. The Court of Appeals for the Second Circuit sustained the Secretary's order[4] and the petition was dismissed in the Seventh Circuit.

The decision of the Court of Appeals for the Fifth Circuit set aside the delisting order as it applied to the certification of FD&C Red No. 32 for external use in the coloring of Florida and Texas oranges.[5] Certiorari was issued to the circuit court and in October, 1958, the case was heard by the United States Supreme Court. On December 15, 1958, the Supreme Court reversed the court of appeals and upheld the Secretary's delisting order.[6]

The Supreme Court decision, seemingly adopting a "harmless per se" doctrine with respect to color additives, has resulted in the present

[3] 21 USCA Sec. 346(b).

[4] *Certified Color Industry Committee et al. v. Secretary of Health, Education and Welfare, Marion B. Folsom*, CCH Food Drug Cosmetic Law Reports ¶ 7367, 236 F. 2d 866 (CA-2, 1956).

[5] *Florida Citrus Exchange v. Folsom*, CCH Food Drug Cosmetic Law Reports ¶ 7404, 246 F. 2d 850 (CA-5, 1957).

[6] *Flemming v. Florida Citrus Exchange*, CCH Food Drug Cosmetic Law Reports ¶ 7468, 79 S. Ct. 160, 358 U. S. 153 (1958).

Food and Drug Administration proposal to delist 17 colors which are alleged to induce adverse physiological reactions in laboratory animals.[7] Consequently, there is an urgent need for an amendment to the current law tempering the illogical and unworkable doctrine adopted by the Supreme Court.

Two Bills Pending

Two bills presently pending before Congress purport to effect this needed amendment. They are the FDA draft bill,[8] introduced in the House of Representatives by Oren Harris, of Arkansas, chairman of the House Committee on Interstate and Foreign Commerce, and the Hill-Goldwater bill,[9] introduced in the Senate by Senator Lister Hill, of Alabama, chairman of the Senate Labor and Public Welfare Committee, on behalf of himself and Senator Barry Goldwater, of Arizona, the ranking minority member of the Labor and Public Welfare Committee. The Hill-Goldwater bill in the Senate is identical to the Harris bill in the House except that the Senate bill does not include the so-called "Delaney cancer clause." [10]

Obviously, as with any proposed amending legislation, certain provisions of the draft FDA bill were objectionable to various segments of the affected industries. Several minor amendments to the original draft prior to its introduction in Congress made the proposed bill somewhat more palatable to industry, although not entirely so. On August 24, 1959, the Hill-Goldwater bill was passed by the Senate.

The drug manufacturer has a significant interest in the proposed color-additive legislation, although he might be considered a Johnny-come-lately to the field. In its chronological history, the use of color in food and cosmetics obviously predated the artificial coloring of drugs. Nevertheless, even in the early days of pharmaceutical manufacturing, color was routinely applied to medicinal products. Since that time, we have seen a tremendous expansion of the use of colors in drug manufacturing.

Using Artificial Colors in Pharmaceutical Industry

The pharmaceutical manufacturer may use an artificial color in a drug product for several reasons. Naturally, one such use is for the purpose of producing an eye-appealing product.

Quite apart from esthetic enhancement and consumer appeal, it is universally agreed that certain colors elicit certain associated effects

[7] 24 *Federal Register* 2873 (April 15, 1959).
[8] H. R. 7624.
[9] S. 2197.
[10] H. R. 7624, Sec. 103(b)

in some persons; hence the color of a drug may have a significant psychological effect on the patient. One would not generally consider a violent chartreuse or a violet color quite appropriate for a preparation designed to alleviate the discomfort of seasickness.

Colors are also used in the pharmaceutical industry to conceal or temper undesirable color effects indigenous to the preparation in its natural state. For example, in a preparation compounded of drug extracts, many variations in the color of the finished product might commonly occur as a result of multiform variegations in the extracts themselves. Therefore, artificial colors are added to provide a uniform hue to the finished product. The *National Formulary*, one of the pharmacist's and pharmaceutical manufacturer's guides to standards for official drug products, calls for the use of ten parts per million of FD&C Red No. 2 as a coloring agent in "Syrup of White Pine Compound." [11]

It is common practice in the industry to make certain pharmaceuticals more palatable by the addition of various flavoring agents. In many instances, a color compatible with the artificial flavor is also added. A cherry-flavored cough preparation, which, ordinarily, would be colorless, may be tinted a deep red to conform the color of the product to its wild-cherry flavor. Other preparations bearing such flavors as wintergreen, butterscotch, peppermint or root beer may also be artificially colored for the same purpose.

Certain drug products contain added color to achieve a desirable cosmetic effect. Preparations for the treatment of certain skin conditions such as acne may, in addition to their therapeutic ingredients, also contain a skintone color to conceal the blemishes caused by the primary condition.

Within the last decade we have seen a tremendous increase in the use of veterinary drugs in animal husbandry—therapeutically, to effect a cure for a disease condition; prophylactically, to prevent the occurrence of the disease; and, as growth-promoting agents, to enhance the rate of growth of a particular animal. These veterinary drug products are often marketed by a manufacturer in the form of a *premix* which, prior to distribution to the ultimate consumer, will be admixed by the feed manufacturer with vast quantities of animal or poultry feed. It is the practice of many manufacturers to color these premixes artificially, thereby enabling the feed manufacturer to determine whether the

[11] *National Formulary* (10th Ed.), p. 638.

medicated premix has been adequately and properly dispersed throughout the finished feed.

Color as Standard of Identification

One of the most important uses of color in drugs is for the purpose of indicating the source of the particular product and identifying the drug in question. The definition of standards in the *United States Pharmacopoeia* for "Phenobarbital Elixir" includes the use of an added color as a standard of identification.[12] Likewise, the *National Formulary* provides that "Bichloride of Mercury Tablets" "must be of a distinctive color, not white."[13] With more and more drug preparations reaching the market, it is readily understandable that a method for enabling the physician and pharmacist to identify a particular drug is most desirable.[14]

These several and varied uses of color additives in drugs and medicines, I believe, give the pharmaceutical-manufacturing industry a material interest in the proposed color legislation.

The drug industry, on the whole, has had relatively few objections to the FDA proposed bill. Some of the industry objections have resulted in modification of the draft legislation by the Food and Drug Administration prior to introduction of the Harris bill in the House of Representatives. Others have not. I shall not attempt a section-by-section analysis of the bills currently before Congress; however, I would like to mention a few portions of this proposed legislation which are of concern to members of the industry which I represent.

Delaney Cancer Clause—Opposition from Segment of Industry

There is opposition on the part of a large segment of the pharmaceutical industry to the inclusion of the often-maligned Delaney cancer clause in color-additives legislation. The Delaney clause, contained in Section 706(b)(5)(B), provides that a color additive shall be considered unsafe and may not be listed "if the additive is found to

[12] *United States Pharmacopoeia* (15th Ed.), p. 531.

[13] *National Formulary* (10th Ed.), p. 371-372.

[14] The Food and Drug Administration recognized the importance of drug identification by color:

"In drugs, color additives are much used for ready identification, thus helping the pharmacist, the physician, the nurse and the patient to avoid dangerous mistakes in choosing the wrong bottle or box. Thus it is in the interest of the consumer that the law be changed so as to make available an adequate supply of colors of the safety of which, for particular uses, the consumer can be assured." (Explanation of principal features and purposes of proposed color-additives amendments of 1959, accompanying H. R. 7624 and letter of transmittal to Sam Rayburn, Speaker of the House of Representatives, May 29, 1959.)

induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal . . .". The clause further provides that a color additive shall be deemed unsafe and may not be listed for a use which will *not* result in its ingestion if, "after tests which are appropriate for the evaluation of the safety of additives for such use, or after other relevant exposure of man or animal to such additive, it is found to induce cancer in man or animal."

The language of the Delaney clause is scientifically illogical and unworkable and it has been suggested that many officials of the Food and Drug Administration are not at all happy with a comparable clause in the recent food-additives law. The provisions of the basic food, drug and cosmetic law and the provisions of the proposed color-additives amendment should certainly result in the desired consumer protection without the necessity of resorting to the intractable language of the Delaney clause.

The original FDA color-additives proposal contained a requirement for "practical and accurate analytical methods for color additives." Observations by two committees of the Pharmaceutical Manufacturers Association, which studied the FDA draft bill, were submitted to Deputy Commissioner of Food and Drugs John L. Harvey, requesting the use of the term "practical analytical methods" in lieu of "practical and accurate analytical methods." A modification requested by HEW effects the change suggested by the Pharmaceutical Manufacturers Association and further provides that analytical methods may be required by the Administration only when necessary.

A substantial element of concern has been expressed by some representatives of the drug-manufacturing industry over Section 706(b)(8) of the proposed bill which grants to the Food and Drug Administration the power to allocate specific colors to different and perhaps competing uses. With respect to this provision, the Pharmaceutical Manufacturers Association, in a communication to the Food and Drug Administration, stated as follows:

> This provision requires the F. D. A. to make determination with respect to the marketability of certain products, a dependence of certain segments of industry on certain additives and the availability of certain additives, all of which will be in practice exceedingly difficult and will demand the accumulation of knowledge and experience which the F. D. A. does not presently possess and which it would not be expected to possess.
>
> In general, we feel that you should turn back to the food additives law and endeavor to follow the format more closely. This law, although not entirely

acceptable to industry, has been worked over, is being better understood and we are endeavoring to live with it. We believe there is no occasion to introduce any new regulatory concepts.

Furthermore, and specifically with respect to pharmaceuticals as distinguished from food and cosmetics, colors are used almost exclusively for the purpose of identity and safety.

Indirectly colors in pharmaceutical products also give clues to antidotes in cases of over-dosages. Legislative and regulatory practices that render it more difficult and sometimes impossible to continue use of colors in harmless amounts in pharmaceutical products can only lead to widespread confusion and concern on the part of physicians and patients. This can result in public harm rather than the intended public good.

The industry's anxiety over the provisions of the bill permitting the allocation of specific colors among competing uses is aggrandized by a relatively short 2½ year "grandfather clause" in the proposed bill, which allows, among other things, the provisional listing of colors from batches certified prior to the effective date of the amendment.[15] The effect of this clause would seem to be to stimulate active retesting of colors by manufacturers of them. Logically, it would be more expedient on the part of color manufacturers to first test and clear those colors comprising the industry's largest market. Since colors are used in the manufacture of foods and cosmetics to a considerably larger extent than in drug manufacture, the pharmaceutical industry might well expect a substantial reduction in the number of colors available to it, unless, of course, the drug industry is prepared to initiate an independent color-testing program of its own.

The objections raised to the bill by drug manufacturers are certainly not extensive, yet they have a significant importance to the pharmaceutical industry. However, it is axiomatic that no bill could be expected completely to satisfy all segments of the industries regulated under it.

While, as a representative of a pharmaceutical manufacturer, I would be most happy to see changes affecting compromises in many of the objectionable features of the bill, I am convinced that the present Senate bill, without the Delaney cancer clause, is a necessary piece of legislation. With many colors proposed for delisting as an aftermath to the *Florida Citrus Exchange* decision,[16] a bill such as the Senate introduction—imperfect, perhaps, as to some details—is much more acceptable than no legislation at all. **[The End]**

[15] H. R. 7624, Sec. 203.

[16] Cited at footnote 6.

Canadian Regulatory and Research Activities in Relation to Foods

THE Food and Drug Directorate is an organization within the Canadian Department of National Health and Welfare responsible for the administration and enforcement of the Food and Drugs Act of Canada, and regulations made under it. The basic function and purpose of the act is to prevent health hazards and frauds that could arise in any way through the consumption and sale of foods, drugs, cosmetics and medical devices. The act is written as criminal law, a subject that under the British North America Act was assigned to federal authority. The constitutionality of the food and drugs act has been recorded in the courts as not coming within the orbit of property and civil rights. Under these circumstances it has not been affected by jurisdictional differences as between provincial and federal authority. The provisions of the act apply to all products over which it possesses authority sold anywhere in Canada. It does not matter whether the products are imported or are of domestic origin.

The food and drugs act is designed essentially in the interests, and for the protection, of consumers. In this respect it is possibly unique among other acts in Canada in controlling foods or drugs. It is not primarily concerned with the expansion or direction of trade nor with the development of new products. In order to obtain a full appreciation of the significance of the relationship of the food and drugs act and regulations to the food industries it is advisable to indicate the definitions of "food" and "sell" as given in the act: (1) "Food includes any article manufactured, sold or represented for use as food for man, chewing gum, and any ingredient that may be mixed with food for any purpose whatsoever." It is noted that this definition excludes food for animals but includes both nutritive and

By L. I. PUGSLEY

Mr. Pugsley, of Canada's Food and Drug Directorate, Ottawa, Presented This Address Before the Canadian Institute of Food Technologists at Toronto on April 17

nonnutritive substances. (2) "Sell includes sell, offer for sale, expose for sale, have in possession for sale and distribute." These definitions are broader than the ones usually given in dictionaries, and any person or organization concerned with the manufacture, distribution and sale of food for man is subject to the requirements as set forth in the food and drugs act and regulations.

Let us now turn to see how the food and drugs act and regulations tend to promote honesty and fair dealings within the food industry and at the same time protect the consumer against health hazards and frauds. The activities of the Food and Drug Directorate are dependent on scientific information and investigations. The food and drugs act provides basic definitions and principles, leaving the details of the administration in the majority of instances to the regulations. This type of delegated legislation—or legislation by regulations—is of special significance in such a complex and technical field as the food industry where frequent changes and variations must be made in order to keep pace with the technological advances. The act delegates to the Governor in Council authority to make regulations respecting the control of the manufacture and sale of foods insofar as this may be necessary for the protection of public health and the prevention of deceptive and dishonest practices. The regulations made under the authority of the act have the same force and effect as if embodied in the act.

In respect to the protection of the public against health hazards, Section 4(a) is of special significance in that it states: "No person shall sell an article of food that has in or upon it any poisonous or harmful substance." Fraud and deception are dealt with in Section 5(i):

> No person shall label, package, treat, process, sell or advertise for sale any food in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety . . . .

The sanitary and hygienic requirements respecting foods are given in Section 4(c) and Section 7: "No person shall sell an article of food that consists in whole or in part of any filthy, putrid, disgusting, rotten, decomposed, or diseased animal or vegetable substance." "No person shall manufacture, prepare, preserve, package, or store for sale any food under unsanitary conditions."

There are a number of other sections of the act and regulations which may be of interest, but the above requirements show the broad scope and authority as it relates to the food industry.

Regulatory Activities

Let us see now how the regulatory activities of the Food and Drug Directorate are carried out and how these fit in with the function and purpose of the act and regulations. It is the general policy of the directorate to exercise "control at the source," and every effort is made to see that the food is safe and wholesome before it reaches the retail outlets. The sanitation section of the act, which was introduced in the 1953 revision, exemplifies this policy.

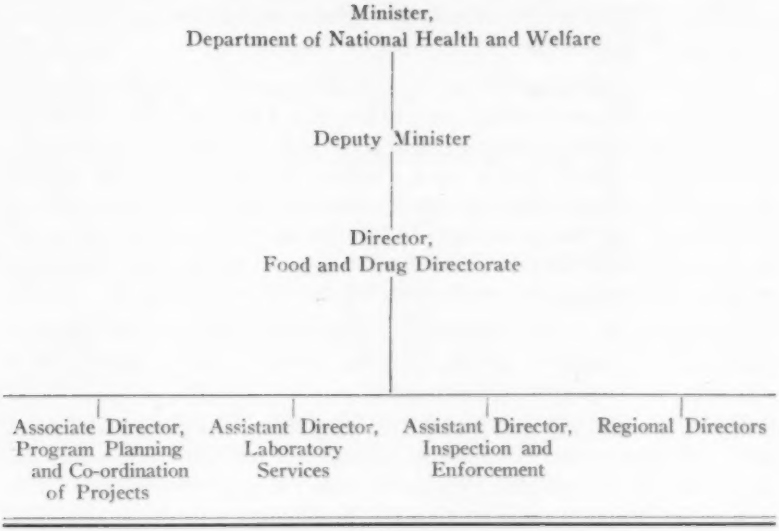
Table I shows levels of administrative responsibility in carrying out the function and purpose of the act.

The director of the Food and Drug Directorate—with the assistance and advice of the associate director, the two assistant directors and the regional directors—reviews each year the regulatory activities and draws up a program with recommendations as to operations for the consideration of the deputy minister who, in turn, advises the minister of the department on all matters which may be of interest from the standpoint of government policy.

In formulating the recommendations on a program of regulatory activities, the administrative group of the directorate is guided by the following principles but whatever is planned must be consistent with the funds and staff allotted to the directorate each year by the govern-

TABLE I

Levels of Administrative Responsibility in Enforcement of Food and Drugs Act



ment for the operation of the Food and Drugs Act and the Proprietary or Patent Medicine Act.

(1) Activities which involve a health hazard or potential health hazard are given first priority.

(2) Activities which are concerned with unsanitary conditions, filth in foods and similar hygienic matters are given second priority.

(3) Activities concerned with deception, fraud and economic cheats are given third priority.

Although every effort is made to keep a balance among these three activities, it is considered that the purpose of the directorate is served more adequately with the staff available if higher priority is given to matters relating to health hazards than to those affecting the pocketbook. With the increasing trend to the production of foods with built-in conveniences and the self-service type of marketing, which demands attractive packaging and featured claims as sales appeal, it is considered that more attention should be given to the

third priority. However, this is impossible with the staff and funds available. The allotment of funds and personnel for the operation of the Food and Drug Directorate in 1958-1959 was $1,792,300 and an established staff of 314. Due to difficulties in recruiting and retaining professional staff, the directorate has been operating the last few years at 6 to 8 per cent below the allotted establishment.

The 1953 revision of the act made specific provision for the inspection of manufacturing plants, and this has resulted in a change of emphasis in the regulatory activities from a "spot-check" type of control at the retail level toward a policy of inspection at the source. It is considered that this has resulted in a more efficient and effective control with the manpower and funds available and at the same time has given the consumer increased protection, especially against health hazards and unhygienic processing and distribution of foods.

Table II shows the number of prosecutions, seizures and voluntary disposals of foodstuffs completed on the domestic market during 1958, classified as to health hazards, filth and decomposition, frauds and cheats. It is noted that the enforcement activities in the health-hazard field constitute approximately 40 per cent of the total actions taken. Applying the philosophy that no human being is expendable, it is considered quite justifiable to make health hazards the major field of activity. The voluntary-disposal column is of interest in showing that in approximately one half of the cases the offending lot of goods was removed from the market without the necessity for legal proceedings. Naturally, each case must be dealt with on its merits and the seriousness of the situation in terms of consumer interest. In many cases it has been the practice to warn manufacturers through trade information letters or by direct communication about violations of the act and regulations and to recommend legal action only when these warnings are not heeded.

There is a large amount of foodstuffs imported into Canada and, in line with inspection of domestic products at the source, an inspection is made of foodstuffs at the time of entry at customs. Foodstuffs found not to comply with the requirements of the act and regulations are refused entry or are reconditioned in such a manner that they are brought into compliance before distribution in Canada. Of the time devoted to foods, approximately 40 per cent is devoted to imported foodstuffs and 60 per cent to the foodstuffs distributed on the domestic market.

TABLE II

Prosecutions, Seizures and Voluntary Disposals of Foods During 1958-1959

	Prosecutions	*Seizures*	*Voluntary Disposals*	*Totals*
Health hazards	7	44	23	74
Filth and decomposition	5	19	24	48
Frauds and cheats	35	9	12	56
Total	47	72	59	178

In order to maintain a surveillance of the food market and to obtain information on potential sources of violations of the act and regulations, it has been the practice to carry out fact-finding investigative surveys on each of the above categories. These have been found very useful in providing background information for subsequent enforcement action as well as providing information on new trade practices and techniques.

The following examples are given of current activities in each of the basic functions:

Pesticide Residues in Foods.—During the past few years there has been considerable interest in the development of new pesticides for use in protecting crops from the ravages of insects and other pests. Unfortunately, the use of these substances, whose purpose is to kill insects and pests, is not without some hazard to the consumer unless caution is exercised in their use. It is residues of these substances in foods which are of concern to the Food and Drug Directorate. Section 4(a) of the act states: "No person shall sell an article of food which has in or upon it any poisonous or harmful substance." In order to assure the safety of foods on which these potent chemicals have been used, discussions were held with a committee of the Agricultural Chemicals Association, and agreement was reached with this group on the type of data and information which should be made available to the directorate in order to ensure that safe residue tolerances could be established for them. Section 24(j) of the act provides authority to make regulations exempting any food from all or any provisions of the act and prescribing the conditions of such exemptions. This authority was utilized in establishing safe residue tolerances for pesticides in foods and to date these have been established for some 50-odd pesticides in approximately 1,100 food items.

The introduction of this legislation has caused a marked increase in the workload of the laboratory and inspection staff of the directorate. It has involved the training of chemists in the regional laboratories in new analytical procedures as well as informing the inspection staff on methods of application, recommendations for use and the properties of these materials in order that instances of misuse and violations may be investigated. This has proved to be a most interesting and challenging task for the staff of the directorate. It has involved close liaison and cooperation with federal, as well as provincial, departments of agriculture in connection with the recommendations made in the spray calendars each year. In 1958, a total of 963 samples of domestic and imported fruits and vegetables were collected by food and drug inspectors and assayed in the laboratories for pesticide residues. It was found that 62 per cent of the samples showed no detectable residues, 97.5 per cent of the samples showed less than 50 per cent of the tolerance, 99.1 per cent of the samples showed less than 100 per cent of the tolerance and 0.9 per cent of the samples exceeded the tolerance.

Screening techniques involving paper and column chromatography have been developed, and the enforcement program in this regulatory activity is quite well established.

Filth in Dried Fruits.—In 1949-1950 an investigative study revealed that a number of dried fruits (figs, dates, olives, cherries, etc.) presented for entry into Canada at customs ports were quite heavily contaminated with insects, insect excreta, molds, and other filth. Prior to this time it had been the practice to procure "grab samples" of these products for examination and to accept or reject the shipment on the basis of the results obtained. It was quite evident that this type of sampling was inadequate, and there was also some indication that Canada had become a dumping ground for shipments refused entry in other countries. In addition, there was evidence of inconsistencies in action taken by the regional offices of the directorate.

In order to obtain a better appreciation of this problem, an investigation was made of the producing and packing practices in the country of origin of some of these dried fruits. This revealed that it was impractical to expect these products to be free of contamination from insects. Therefore, it was necessary to establish a tolerance or level of insect contamination which would conform to good commercial packing conditions. To establish and maintain a fair and

uniform enforcement of such a tolerance it was necessary to set up a proper sampling and examination scheme. In the case of dried figs and dates these are usually imported in carload lots of 500-700 boxes containing 70 pounds of the dried fruit or by freighter carrying as many as 100,000 to 200,000 boxes.

In order to obtain a statistically valid sampling scheme it was necessary to study the distribution of defective fruit between and within boxes of these products. This was done and applied to different sampling schemes, for example, sequential, single and double sampling. It was essential to have a scheme which was practical in operation and which would give the importer a decision promptly, since all import shipments are subject to demurrage charges 48 to 72 hours after entry at customs. A double sampling scheme was found to be the most practical one to use under the circumstances. By reducing the acceptance number, it was found after considerable experience that very good or very bad lots could be disposed of by means of a screening procedure and the full sampling and examination applied only where the levels of defectives were close to the tolerance. Using the screening procedure, a lot of dates or figs can be readily disposed of in four to six hours by one analyst after the samples are procured.

A number of difficult problems developed in working out the details of the sampling and examination procedures. Training courses were organized for the field staff and specifications were drawn up for defective fruit. It was necessary to introduce the use of wide-field microscopes in order to have a uniform level of magnification for the detection of defectives. Since this sampling and examination scheme was placed in operation, there has been no instance where the re-examination of a shipment did not confirm the first examination, whether it was done by the same people or in other food and drug laboratories. As a result of this work, there has been a marked reduction in the insect contamination of dried fruit entering Canada.

Adulteration of Dairy Products with Vegetable Oils.—A type of violation involving serious fraud was encountered a few years ago concerning the addition of vegetable oils to butterfat and the replacement with vegetable oils of butterfat in evaporated milk. In both cases the vegetable oil was added at levels which defied detection by known methods. It was evident that sufficient vegetable oil could be added to these dairy products to make it a profitable venture because com-

plaints were received from ethical producers that it was impossible to meet the price of these unethical competitors. It was evident that some new criterion was necessary to prove the presence of foreign fats in dairy products.

It happened at this time that the research laboratories were developing a chemical method for the estimation of vitamin E in wheat germ oil. A study of the vitamin E, or tocopherol, content of a number of vegetable oils showed that the majority contained considerably more of this constituent than did animal fats. When the vitamin E method was applied to samples of the suspected butter, tocopherol values three to four times that expected for butterfat were obtained. Before proceeding with action to curb this violation it was necessary to study the seasonal variations in tocopherol content of butter. Authentic samples from across Canada were analyzed and, from the results obtained, a maximum level of tocopherol in butter oil was established by regulation. This allowed the directorate to proceed with seizures of the suspected lots of butter and with prosecution of the offenders.

An interesting sidelight occurred in the disposal of the seizures of the foods containing these mixtures of fat, since they were not harmful but were economic cheats. It was difficult to dispose of them in other countries because most countries have a standard for butter which does not permit the inclusion of vegetable oil. Disposition was finally made as a product containing vegetable oil for animal feed and for use in the manufacture of confectionery. Since seizures are the property of the government, the directorate frequently finds it difficult to recommend disposal of foodstuffs which are in violation of a standard but otherwise wholesome, especially where there is no suitable method to bring the food into compliance or when it is not normally used as animal feed.

Some enterprising individuals have attempted to take advantage of the natural seasonal variations in the tocopherol content of butter oil for the addition of vegetable oils to dairy products and it has been necessary to introduce further refinements in methods of detection of adulteration. This has involved the use of differential analysis using infrared absorption and column chromatography. With this procedure it is considered that levels of adulteration can be detected that are not profitable to producers of such products.

Research Activities

The research activities of the laboratories of the Food and Drug Directorate are primarily in the field of methodology. Some fundamental projects are pursued but of necessity the major activities are in the applied research field. Every effort is made to keep abreast of new and promising developments in foods and drugs in order to have information available for appraisal of the situation in the interests of the consumers. The administration and enforcement of the Food and Drugs Act depends in a large measure on the availability of scientific information and precise methods.

Research and investigative work form a substantial part of the job of the central laboratories at Ottawa and to a lesser degree in the regional laboratories, where the analytical work required in the enforcement program forms the major activity. In such a broad field as is embodied under the Food and Drugs Act, a number of different scientific disciplines must be available to supply the necessary information and methods for its administration. The Ottawa laboratory is divided into the following sections: pharmacology, physiology, nutrition, microbiology, pathology, biometrics, biophysics, organic chemistry, food chemistry and pharmaceutical chemistry, with a group of scientists in each of the sections specializing in the respective field. The larger sections are subdivided into units. For example, in the food-chemistry section there is a group specializing in the development of methods for determining pesticide residues in foods, another group on spectrophotometric methods, and a third group developing methods for the detection of filth in foods. It would be difficult to outline the various research projects on foodstuffs in progress at present in the various sections; therefore, the following have been selected in order to indicate the type of work pursued.

Development of Criteria for Evaluating Protein Quality of Foods.—During the past few years there has been a marked trend toward the importance of the protein content of diets. In protein nutrition there has been general acceptance of the term "high quality" for proteins of animal origin such as meat, milk and eggs. On the other hand, cereal proteins have been regarded as having a relatively lower quality due to the absence of certain essential amino acids in them. At the same time there have been rapid advances in making commercially available certain synthetic amino acids which may be added to cereal proteins

to make them comparable to animal proteins with respect to amino acid content.

There has also been a growing practice of blending different foods to enhance the quality of the final product. It is well known that different methods of processing foods have a marked effect on the quality of the proteins, and one cannot determine by chemical analyses alone the quality of a protein food. In view of these developments and the claims made for certain foods, it was evident that a practical method of evaluating protein quality was needed in order to ensure that consumers were not being misled.

The vitamin and nutrition section of the Ottawa laboratory has been engaged in this project. It has developed an assay method using weanling rats where the quality of a protein food can be measused against a reference protein—in this case a standard preparation of casein. Protein efficiency ratio (PER) values have been obtained for a number of foods. By multiplying the PER of the food by the grams of protein obtained from a reasonable daily intake of the food, a protein rating may be obtained showing whether this food is a good source of protein or a poor one. This method offers considerable promise in placing foods in their proper perspective with respect to their protein contribution to a diet. The cereal and animal proteins fall into two distinct groups. When one is blended with the other or amino acids added to a food, one can readily determine the contribution of the final product to the over-all protein intake. This work has been of considerable significance in the assessment of advertising claims for various food items.

Physiochemical Characterization of Essential Oils and Their Derivatives.—During the past few years considerable interest has been taken in the addition of chemicals to foods or food additives. These substances may be defined as "materials added to or used in the manufacture or formulation of foodstuffs for the purpose of imparting some desired quality or serving some functional purpose." The essential oils and other flavors used in foods come within this definition.

In the course of the program of work of the laboratories in the food-additives field, it was considered essential to study some of the properties of the essential oils and flavors. The flavoring of foods has been more an art than an exact science, and it was apparent after a review of the literature that often information was not available on methods of identifying and characterizing many of the substances

used as flavors. In the majority of instances flavors are present in very small amounts and thus they evade the classical methods of analyses involving precipitation, titration and colorimetry.

With the introduction of instrumentation, utilizing infrared and ultraviolet absorption, paper chromatography and vapor phase fractograms, an opportunity was available to obtain data and information on this group of food additives. The organic chemistry section at the Ottawa laboratory has been engaged in a project to establish, by means of instrumentation techniques and chromatography, useful parameters of identity and reference guides for a group of the essential oils and flavoring substances. One of the marked advantages of these instrumentation procedures is that the experimental data obtained may be traced automatically in the form of a chart giving a permanent record of the analysis. This enables one to study some of the fundamental correlations between configuration and physical properties as well as to obtain information on molecular structure. This study is providing valuable data on the still little-understood relationship between chemical constitution and the odoriferous properties of aromatic compounds.

Development of Screening Methods for Detection of Violations of Regulations

Section 21 of the Food and Drugs Act provides authority for a food and drug inspector to enter any place where, on reasonable grounds, he believes there are any articles to which the act or regulations apply, to examine such articles and take samples of anything he reasonably believes is used in the manufacture, preparation, preservation, packaging or storage of foodstuffs. Authority is provided to seize and detain for such time as may be necessary any article by means of or in relation to which the inspector reasonably believes any provisions of the act or regulations have been violated.

The application of this authority requires considerable discretion and prudence on the part of the inspectors. Before seizing a lot of foodstuffs, an inspector must have some reasonable grounds for his action; it is one of the functions of the laboratories to provide him with the information and tools to carry out his duties.

For a number of years the directorate has had a difficult problem in the enforcement of the requirements prohibiting the use of sulfites in meat products. It appears to be quite well known among producers

of prepared meats that the addition of a small amount of sodium bisulfite to meat scrapes will brighten up the color of the product and make it appear as if made from fresh meat. The regulations under the act declare meat adulterated if it contains sulfites.

One of the problems concerned in the enforcement of this regulation was the time required between the sampling and the analyses of the suspected products. In many instances the inspectors are located 500 miles from the laboratory and, naturally, by the time an inspector received a laboratory report the suspected meat had all disappeared. Where prosecutions were instituted the courts levied nominal fines, and in some cases it appeared that these were being looked upon as a license fee to use sulfites. It was evident that a more effective enforcement of the requirements could be made if the inspector had sufficient evidence to seize the suspected lot of meat at the time he procured the sample.

The chemists of the Toronto regional laboratory undertook a study of this problem and provided the inspection staff with a portable kit for testing for the presence of sulfites in meats. The method is based on the displacement of sulfur dioxide from a measured portion of meat by adding hydrochloric acid to it. The outlet of the bottle carries a thistle tube containing a barium-chloride-iodine solution. The sulfur dioxide, if present, is removed from the reaction flask by blowing a gentle stream of air through the solution, and the gas passes through the barium-chloride-iodine solution. An estimate of the amount of sulfite present can be obtained by determining the time required to dispel the iodine color of the barium-chloride-iodine solution. The test can be completed in a few minutes. Where sulfites are found by using this screening procedure, the lot of meat is withdrawn from sale by placing it under seizure. At the same time official samples are taken for analysis by the standard titration procedure. The interference with the sale of a day's supply of meat has had a very salutary effect in preventing repeat violations through the addition of sulfites to meat. At present the use of starch-iodine paper as the indicator instead of the barium-chloride-iodine solution is being studied as a refinement of the test.

Use of Ionizing Radiations in Preservation of Foods

In order that the directorate may have data and information on the effects of radiations on foods, projects in this field were initiated in collaboration with Atomic Energy Limited. One of these projects

consisted of a study of the effects of gamma radiations on the ascorbic acid, starch and sugar content of potatoes. At the same time, the horticulture division of the department of agriculture studied the effects on sprouting and culinary properties. The only effect of the radiations that could be detected was an initial increase in the reducing sugars of the potatoes as compared to controls. Storage time and temperature influenced the ascorbic acid, sugar and starch content to a much greater extent than did the radiations. Effective inhibition of sprouting was obtained with a radiation dose of 8.5 Krep at a storage temperature of 68 degrees Fahrenheit.

It is known that radiations have a marked ability to cause mutation in micro-organisms. In this connection the microbiology section of the laboratory has undertaken a study to determine the rate of development of resistance in a number of species of bacteria associated with spoilage, pathogenicity and toxin formation in foods. Multiple exposure causes an increase in resistance to radiations in several species. This study is providing valuable information in the event that preservation by radiation may become a practical procedure.

The problem of world-wide radioactive fallout from weapon-test operations has aroused considerable public attention during the past few years. In order to have data and information available on the potential hazards of radioactive fallout, a project is under way comparing the beta and gamma radiations emitted from a variety of foods preserved prior to the activities in the nuclear-weapon-testing field with those emitted from foods packed during the past five years. This project has presented, in obtaining precise values, a number of difficult problems in methodology. The preliminary values obtained to date indicate there is no evidence of hazard with the criteria established for potential hazardous effects of radiations. **[The End]**

• FOODS FOR SUGAR-RESTRICTED DIETS—FDA ORDER •

Improvement in the quality and labeling of foods for persons on sugar-restricted diets is the objective of a Food and Drug Administration order issued on October 31. The order established definitions and standards of identity fixing the composition of artificially sweetened jams, jellies and preserves.

The new standards reduce variations in the composition of such fruit products and specify the type of labeling to be used. The order was based on proposals of the National Preservers Association, as published in the June 20, 1959 *Federal Register*, and on comments received from interested persons. The standards will become effective 90 days from the date of issuance of the order unless stayed.

CHRISTOPHER

COMMENTS

Thomas W. Christopher is associate dean and professor of law at Emory University, Atlanta, Georgia.

Florida Amendments.—Florida has amended its food and drug statute in several material respects,[1] to take effect on January 15, 1961.

Regulation of food is to be under the commissioner of agriculture and regulation of drugs and cosmetics under the state board of health. An unusual section provides for the registration of packaged foods, drugs, devices and cosmetics, and the filing of specimens of labels and catalogues; producers are to be charged fees in this connection. This provision should be a boon to filing-cabinet salesmen.

The act states that one of its policies and purposes is to achieve uniformity with United States food and drug and Federal Trade Commission requirements; the food-standards section requires uniformity with federal standards "so far as practicable." Here, since discretion is left in the state official, there does not appear to be any delegation of state power, and so no serious constitutional question arises in this regard. If the statute merely adopted future federal food standards, there might be a question of invalid delegation.

An interesting provision deals with corn meal. The misbranding-of-food section states that a food is misbranded if "its labeling is false or misleading in any particular . . . ." The section then makes a single exception, namely water-ground corn meal. It provides that "corn meal shall not be considered misbranded because of its being labeled 'Water Ground', where such corn meal so labeled shall have been ground on rocks having a diameter of not less than forty-two inches and which revolve . . . at a speed not greater than one hundred and eighty-six revolutions per minute."

[1] CCH Food Drug Cosmetic Law Reports ¶ 34,301.

Thus, water-ground meal need not be water ground. One may wonder how the label "Genuine Water-Ground Corn Meal" would be treated under this provision. Must the power here be water?

Another provision empowers the commissioner to suspend or revoke any registration of a product for the violation of *any* provision of the act. The effect of such suspension or revocation apparently would be to eliminate that product from the Florida market. This is an unusual penalty provision, and could be a strong weapon. A hearing is provided, but no mention is made of court review—so, at least in theory, a minor violation could be used to close up a factory.

Trading Stamps.—A New Jersey court has ruled that unredeemed trading stamps do not escheat to the state.[2] The decision appears to be put on the basis that, on the facts, the purchaser of goods—as a prerequisite to his using his stamps—must accumulate a minimum number before he has any rights to redeem and also that the stamps are not transferable by the purchaser. Therefore, in the absence of proof by the state that the billions of unredeemed stamps belong to persons who have the minimum number, no right arises in the purchaser or in the state. Since the stamps are not transferable, the fact that the billions of stamps would in the aggregate fill countless stamp books is not material.

• VITAMIN E CLAIMS—FDA CAUTIONS CONSUMERS •

The Food and Drug Administration recently cautioned consumers against wild claims concerning products purporting to be sources of vitamin E. Since the daily diet provides more than adequate amounts of the vitamin for the average individual, FDA noted, supplementing it with the vitamin is not necessary. The announcement said: "Any claim in the labeling of drugs or foods offered for special dietary use by reason of Vitamin E, that there is need for dietary supplementation with Vitamin E, will be considered false."

The note of caution accompanied an announcement in the October 29 issue of *Federal Register* to the effect that products represented as containing vitamin E are no longer required to bear a label statement that the need for that vitamin in human nutrition has not been established. It has now been established that vitamin E is needed in the physiological processes of the human body, according to FDA.

[2] *State v. Sperry & Hutchinson Company*, 153 A. 2d 691 (N. J. Super. Ct., App. Div., 1959).

WASHINGTON—Continued from page 684

Calcium pantothenate.
Calcium phosphate (mono-, di-, tribasic).
Calcium sulfate.
Carotene.
Ferric phosphate.
Ferric pyrophosphate.
Ferric sodium pyrophosphate.
Ferrous sulfate.
Iron, reduced.
l-Lysine monohydrochloride.
Niacin.
Niacinamide.
D-Pantothenyl alcohol.
Potassium chloride.
Pyridoxine hydrochloride.
Riboflavin.
Riboflavin-5-phosphate.
Sodium pantothenate.
Sodium phosphate (mono-, di-, tribasic).
Thiamine hydrochloride.
Thiamine mononitrate.
Tocopherols.
a-Tocopherol acetate.
Vitamin A.
Vitamin A acetate.
Vitamin A palmitate.
Vitamin B_{12}.
Vitamin D_2.
Vitamin D_3.

SEQUESTRANTS

(For the purpose of this list, no attempt has been made to designate those sequestrants which may also function as chemical preservatives)
Calcium acetate.
Calcium chloride.
Calcium citrate.
Calcium diacetate.
Calcium gluconate.

STATEMENT REQUIRED BY THE ACT OF AUGUST 24, 1912, AS AMENDED BY THE ACTS OF MARCH 3, 1933, AND JULY 2, 1946 (Title 39, United States Code, Section 233) SHOWING THE OWNERSHIP, MANAGEMENT, AND CIRCULATION OF

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1. The names and addresses of the publisher, editor, managing editor, and business managers are:

Publisher: Commerce Clearing House, Inc., Chicago 46, Illinois.

Editor: Henry L. Stewart, Chicago 46, Illinois.

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3. The known bondholders, mortgagees, and other security holders owning or holding 1 percent or more of total amount of bonds, mortgages, or other securities are: (If there are none, so state.) None.

4. Paragraphs 2 and 3 include, in cases where the stockholder or security holder appears upon the books of the company as trustee or in any other fiduciary relation, the name of the person or corporation for whom such trustee is acting; also the statements in the two paragraphs show the affiant's full knowledge and belief as to the circumstances and conditions under which stockholders and security holders who do not appear upon the books of the company as trustees, hold stock and securities in a capacity other than that of a bona fide owner.

5. The average number of copies of each issue of this publication sold or distributed, through the mails or otherwise, to paid subscribers during the 12 months preceding the date shown above was: (This information is required from daily, weekly, semiweekly, and triweekly newspapers only.)

Henry L. Stewart
(Signature of editor, publisher, business manager, or owner)

Sworn to and subscribed before me this 18th day of September, 1959.

[Seal] Lester Johnson
(My commission expires Nov. 14, 1961)

Calcium hexametaphosphate.
Calcium phytate.
Citric acid.
Dipotassium phosphate.
Disodium phosphate.
Monocalcium acid phosphate.
Monoisopropyl citrate.
Potassium citrate.
Sodium acid phosphate.
Sodium citrate.
Sodium diacetate.
Sodium gluconate.
Sodium hexametaphosphate.
Sodium metaphosphate.
Sodium phosphate (mono-, di-, tribasic-).
Sodium potassium tartrate.
Sodium pyrophosphate.
Sodium tartrate.
Sodium tetrapyrophosphate.
Sodium tripolyphosphate.
Tartaric acid.

STABILIZERS

Agar-agar.
Carob bean gum (locust bean gum).
Carrageenin.
Guar gum.

Product	*Tolerance*	*Specific Uses or Restrictions*
	ANTICAKING AGENTS	
Aluminum calcium silicate	2 percent	In table salt.
Calcium silicate	5 percent	In baking powder.
Calcium silicate	2 percent	In table salt.
Magnesium silicate	Do.	In table salt.
Tricalcium silicate	Do.	In table salt.
	CHEMICAL PRESERVATIVES	
Benzoic acid	0.1 percent	.....
Butylated hydroxyanisole	Total content of antioxidants not over 0.02 percent of fat or oil content, including essential (volatile) oil content, of food.	.....
Butylated hydroxytoluene	Do.	.....
Caprylic acid	.....	In cheese wraps.
Dilauryl thiodipropionate	Total content of antioxidants not over 0.02 percent of fat or oil content, including essential (volatile) oil content of the food.	.....
Gum guaiac	0.1 percent (equivalent antioxidant activity 0.01 percent.)	In edible fats or oils.
Nordihydroguaiaretic acid	Total content of antioxidants not over 0.02 percent of fat or oil content, including essential (volatile) oil content of the food.	.....
Potassium bisulfite	.....	Not in meats or in foods recognizable as a source of vitamin B_1.
Potassium metabisulfite	.....	Do.

Product	*Tolerance*	*Specific Uses or Restrictions*
Propyl gallate	Total content of antioxidants not over 0.02 percent of fat or oil content, including essential (volatile) oil content of the food.	.....
Sodium benzoate	0.1 percent	.....
Sodium bisulfite	.....	Not in meats or in foods recognizable as a source of vitamin B_1.
Sodium metabisulfite	.....	Do.
Sodium sulfite	.....	Do.
Sulfur dioxide	.....	Do.
Thiodipropionic acid	Total content of antioxidants not over 0.02 percent of fat or oil content, including essential (volatile) oil content of the food.	.....
EMULSIFYING AGENTS		
Cholic acid	0.1 percent	Dried egg whites.
Desoxycholic acid	Do.	Do.
Glycocholic acid	Do.	Do.
Ox bile extract	Do.	Do.
Taurocholic acid (or its sodium salt)	Do.	Do.
MISCELLANEOUS		
Caffeine	0.02 percent	In cola type beverages.
Ethyl formate	0.0015 percent	As fumigant for cashew nuts.
Magnesium stearate	.....	As migratory substance from packaging materials when used as a stabilizer.
Sorbitol	7.0 percent	In foods for special dietary use.
Triethyl citrate	0.25 percent	Egg whites.
NUTRIENTS		
Copper gluconate	0.005 percent	.....
Cuprous iodide	0.01 percent	In table salt as a source of dietary iodine.
Potassium iodide	Do.	Do.
SEQUESTRANTS[1]		
Isopropyl citrate	0.02 percent	.....
Sodium thiosulfate	0.1 percent	In salt.
Stearyl citrate	0.15 percent	.....

[1] For the purpose of this list, no attempt has been made to designate those sequestrants which may also function as chemical preservatives.

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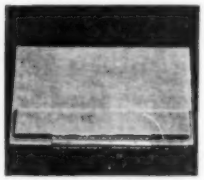
CCH's *Long-Lasting* ACCESSORIES

Order Yours Today!

Simple, three-way adjustment for comfortable reading angle



Folds flat—slips into desk drawer until needed

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- *clears your desk for action*
- *puts "ease" in your work*

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Send for our own use or distribution and not for resale ..... CCH "Eye-Saver" Reading Easels at $4.75 each, postpaid.

☐ **Remittance herewith** ☐ **Send bill**

Send CCH Zipper Cases indicated below:

☐ **We enclose $ ..... for ..... CCH Zipper Cases at $9.75 each, postpaid. Gold stamp—one line, maximum 18 characters—as follows:**

Please print or typewrite name to be gold stamped.

(1). .....

(2). .....

(3). .....

We understand gold-stamped cases are not returnable.

☐ **Send us ..... CCH Zipper Cases, without gold stamping, billed at $9.75 each, postpaid. We understand we may return the cases for full credit within 15 days after receipt, if not satisfied.**

Signature & Title .....

Firm .....

Attention .....

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City, Zone & State .....

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